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Attorneys for Plaintiff  
ALIGN TECHNOLOGY, INC.

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

ALIGN TECHNOLOGY, INC.,

Plaintiff,

v.

SMILEDIRECTCLUB, LLC; SDC  
FINANCIAL LLC;  
SMILEDIRECTCLUB, INC; DAVID  
KATZMAN; STEVEN KATZMAN;  
JEFFREY SULITZER;  
SULITZER PROFESSIONAL  
CORPORATION; ALEX FENKELL;  
JORDAN KATZMAN; CAMELOT  
VENTURE GROUP.

Defendants

Case No.

**[REDACTED]  
COMPLAINT FOR FALSE,  
MISLEADING, AND FRAUDULENT  
ADVERTISING, AS WELL AS A  
PATTERN AND PRACTICE OF  
WIRE FRAUD AND MAIL FRAUD**

**JURY TRIAL DEMANDED**

SmileDirectClub (SmileDirectClub LLC, SDC Financial LLC, and SmileDirectClub, Inc., collectively “SDC”) is a company built on a lie. From day one, SDC advertised its aligners and “services” with false and fraudulent claims, telling consumers that SDC patients get real medical care from SDC-affiliated dentists and orthodontists. The other defendants—investors and principals of SDC—have engaged in a scheme to perpetuate these false advertisements (which amount to a pattern and practice of wire fraud and mail fraud). Align Technology, Inc. (“Align”) asks the Court for compensation for the damage caused to its business, and both preliminary and permanent injunctions prohibiting further false advertisements.

### NATURE OF ACTION

1. Align’s revolutionary invention—the Invisalign® system—empowers dentists and orthodontists (“doctors”) to correct teeth with clear plastic aligners rather than unsightly and uncomfortable wire-and-bracket braces.

2. Smile Direct Club created a direct-to-consumer (“DTC”) competitor to Invisalign® aligners, claiming to offer consumers an equivalent product through which SDC’s dentists supposedly treat and monitor patients digitally from afar.

3. Regrettably, SDC founded its business on a dangerous lie—telling consumers through television, online, email, print, and retail advertising that they will receive actual medical supervision from actual doctors, responsible for their wellbeing. SDC promises patients “the same level of care” they receive from in-person medical care:<sup>1</sup>

**“With SmileDirectClub, you receive the same level of care from any treating dentist or orthodontist, with the convenience that comes with online access.”**

Jeffrey Sulitzer, DMD, Chief Clinical Officer at SmileDirectClub.

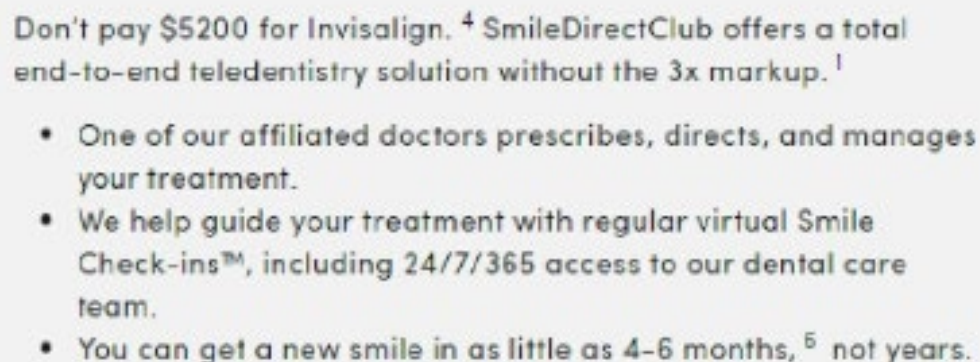


<sup>1</sup> [https://smiledirectclub.com/how\\_it\\_works/dentists/](https://smiledirectclub.com/how_it_works/dentists/) (last visited Nov. 30, 2022).

4. Orthodontic treatment (whether with metal braces or clear aligners) involves moving teeth through bone to create straighter teeth and better bite alignment. Orthodontic treatment occurs over months as applied forces push teeth through bones in patients' mouths, as well as moving patients' jaws as needed.

5. Even with mail-order aligners, consumers rightfully want to ensure they will receive safe and effective medical supervision with SDC's at-home clear aligners. SDC recognizes its prospective customers want to know "Will a real doctor actually lead my treatment?" SDC answers that *frequently asked question* on its website by claiming "Every aspect of clear aligner treatment with SmileDirectClub—from the creation of the treatment plan through the retention phase—is prescribed and managed by an assigned state-licensed dentist or orthodontist."<sup>2</sup>

6. Align's Invisalign® aligners are prescribed and managed by in-office dentists and orthodontists. SDC competes directly with Align's Invisalign® system sold through doctors, claiming for years that SDC provides equivalent level of medical care and supervision as doctors that prescribe Invisalign® clear aligners. SDC's website has long urged consumers: "Don't pay \$5200 for Invisalign," because SDC's "Doctor-directed" care is available and "[o]ne of our affiliated doctors prescribes, directs, and manages your treatment."<sup>3</sup>



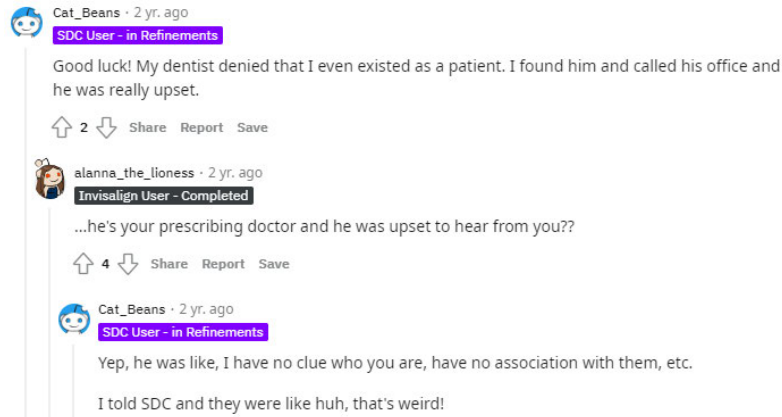
Don't pay \$5200 for Invisalign. <sup>4</sup> SmileDirectClub offers a total end-to-end teledentistry solution without the 3x markup. <sup>1</sup>

- One of our affiliated doctors prescribes, directs, and manages your treatment.
- We help guide your treatment with regular virtual Smile Check-ins™, including 24/7/365 access to our dental care team.
- You can get a new smile in as little as 4-6 months, <sup>5</sup> not years.

<sup>2</sup> *Id.*

<sup>3</sup> Ex. 1, Capture of "SDC vs. Invisalign" Tab of Smile Direct Club Website, <https://smiledirectclub.com/why-smile-direct-club/> (Captured Jan. 11, 2022).

7. SDC's ads claim that actual doctors manage SDC clear aligner treatment. These ads are false. Many SDC patients have attempted to talk to their so-called treating doctors (to no avail), and some have tried to visit their assigned doctor only for that doctor to "den[y] the [person] ever existed as a patient."<sup>4</sup>



8. SDC patients have had to consult real doctors to fix the damage SDC aligners have caused. Many of these consulted doctors have been appalled at SDC's (lack of) care, commenting that certain patients would not have been approved for SDC treatment if a doctor actually examined the teeth. For example, one orthodontist—who was consulted by an SDC patient—reported to the FDA:

It is my assessment as an orthodontic professional that a medical device is being prescribed to straighten [a patient's] teeth without being under the supervision of a trained dentist/ orthodontist. She was charged \$2000 [by SDC] for a service that left her teeth crooked, the heights of her front teeth are completely uneven, the back teeth do not come together properly and several of those teeth are interfering with each other, and the supposed 'doctor' diagnosing and assisting with this case left 2 unerupted permanent teeth under the gumlines and existing baby teeth . . . .<sup>5</sup>

<sup>4</sup> [https://www.reddit.com/r/smiledirectclub/comments/hu3ev5/contacting\\_assigned\\_dentist/](https://www.reddit.com/r/smiledirectclub/comments/hu3ev5/contacting_assigned_dentist/) (last visited Dec. 1, 2022).

<sup>5</sup> Ex. 2, MAUDE Adverse Event Report, No. MW5090525 (Oct. 18, 2019). Maude adverse event reports are publicly available on the FDA's website. See <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>.



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13 10. SDC knows that its misrepresentations are false. SDC furthers its  
14 scheme to defraud consumers by repeating its lies about doctor involvement to state  
15 and federal regulators, shareholders, and insurance companies, among others. What  
16 is more, SDC furthers its fraudulent scheme by forcing dissatisfied customers to  
17 arbitrate disputes and sign non-disclosure agreements if they want a refund.<sup>6</sup> SDC  
18 thus uses lies to get customers and legal tricks to keep them quiet.


19 11. SDC's fraudulent advertising related to doctor-managed care causes  
20 real harm to real people. Unaware of the false and misleading nature of SDC's  
21 claims, consumers are unwittingly tricked into purchasing SDC's aligners on the  
22 (erroneous) premise that they will receive true doctor-supervised care (as they would  
23 get with Align's Invisalign® system). This deception has devastated some consumers,  
24 who have suffered permanent bone loss, broken and lost teeth, and misaligned bites  
25

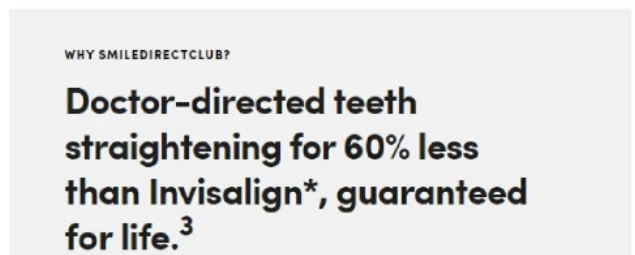
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26 <sup>6</sup> Griffith & Eavis, *This Company Says It Will Fix Your Smile, It May Shush You if It*  
27 *Doesn't*, N.Y. Times, Jan. 21, 2020, <https://www.nytimes.com/2020/01/21/technology/smiledirectclub-smile-nda.html> (last visited Dec. 1, 2022).  
28

that have required expensive and painful treatment to fix, if they can be fixed at all. For example, one former SDC patient reported to the FDA that she suffered “**permanent damage** . . . due to Smile Direct Club not taking in account the bone around the teeth” and she regretted not getting “Invisalign in the first place.”<sup>7</sup>

12. SDC’s false claims have not just caused physical harm, including disfigurement, to real people (i.e. not giving the promised smile people love). SDC’s fraudulent ads have also harmed Align’s bottom line. Align has a strong position in the teeth-straightening market, especially with consumers interested in clear aligners, due to Align’s superior technology, brand recognition, and goodwill earned through decades of selling clear aligners under the protection of U.S. Patents.

13. SDC’s false advertising has directly caused Align to lose sales and continues to cost Align millions of dollars. Until very recently SDC has featured an “SDC v. Invisalign” page prominently on SDC’s website, with a claim that SDC provides “Doctor-directed teeth straightening for 60% less than Invisalign.”<sup>8</sup> SDC would not target Invisalign® customers with tens of millions of dollars in false representations related to doctor-directed care if SDC did not expect to persuade customers who would otherwise purchase Invisalign® aligners. The Better Business Bureau’s National Advertising Division  SDC vs Invisalign How It Works Results Pricing Insurance SDC Teens has repeatedly found advertisements like these to be misleading without clarification, yet SDC still repeats similar false advertisements elsewhere.<sup>9</sup>



<sup>7</sup> Ex. 4, MAUDE Adverse Event Report, No. MW5093023 (Feb. 12, 2020) (emphasis added).

<sup>8</sup> Ex. 1, Capture of “SDC vs. Invisalign” Tab of Smile Direct Club Website, <https://smiledirectclub.com/why-smile-direct-club/> (Captured Jan. 11, 2022).

<sup>9</sup> <https://bbbprograms.org/media-center/dd/smiledirectclub-60-less-claim> (last visited Dec. 14, 2022).

1           14.     SDC went so far as to launch a “Challenger” campaign “targeted  
2 directly at Invisalign’s customer base.”<sup>10</sup> Numerous “Invisalign v. SDC” forums exist  
3 online, showing consumers who buy SDC aligners would otherwise frequently  
4 purchase Invisalign® clear aligners from actual doctors.

5           15.     Every day, SDC markets and mails its aligners to unwitting consumers,  
6 duping them with advertisements that intentionally mislead them into believing  
7 that they will receive the same level of medical care and obtain comparable  
8 outcomes as braces and Invisalign® after their purchase. SDC’s bait-and-switch  
9 advertisements directly harm Align’s sales of its Invisalign® system. In addition,  
10 SDC’s misrepresentations erode Align’s hard-earned goodwill and reputation by  
11 causing consumers to associate clear aligners with often painful and botched results.

12           16.     The fact that SDC targeted its ads at Invisalign® consumers manifests  
13 that a large percentage of SDC customers would choose Invisalign® if they knew the  
14 truth—that SDC aligners can be hazardous and are not medically supervised. SDC  
15 sold aligners to 1,160,423 consumers between 2019 and 2021 alone.<sup>11</sup> If only 30% of  
16 these consumers would have purchased Invisalign®, Align’s lost profits for those  
17 years would have exceeded hundreds of millions of dollars.

18           17.     SDC’s false advertising constitutes “false or misleading  
19 representation[s] of fact” subject to suit under the Lanham Act. 15 U.S.C.  
20 § 1125(a)(1). In addition, SDC and affiliated defendants know that their  
21 advertisements are in fact false and that consumers rely on them. The non-SDC  
22 defendants are thus (as detailed further below) engaged in a pattern and practice of  
23 mail and wire fraud, which is subject to suit as racketeering under the Civil RICO  
24 statute, 18 U.S.C. § 1964(c), and Arizona Revised Stat. § 13–2314.04(A).

25           <sup>10</sup> [https://seekingalpha.com/article/4447527-smiledirectclubs-sdc-ceo-david-katzman-](https://seekingalpha.com/article/4447527-smiledirectclubs-sdc-ceo-david-katzman-on-q2-2021-results-earnings-call-transcript)  
26 [on-q2-2021-results-earnings-call-transcript](https://seekingalpha.com/article/4447527-smiledirectclubs-sdc-ceo-david-katzman-on-q2-2021-results-earnings-call-transcript) (last visited Dec. 1, 2022).

27           <sup>11</sup> SDC 2020 Form 10-K at 57 (<https://investors.smiledirectclub.com/node/7586/html>);  
28 SDC Form 2021 10-K at 64 (<https://investors.smiledirectclub.com/node/8621/html>).

**PARTIES**

**A. Plaintiff Align Technology**

18. Align is a Delaware corporation with its principal place of business in Tempe, Arizona. Align invented the technology for using clear plastic aligners to straighten teeth, disrupting the wires-and-brackets paradigm through which doctors manually moved teeth and corrected patients' bites with metal braces. For over 20 years, Align has developed and sold clear aligners to an ever-growing consumer base (many who previously would have purchased traditional metal braces) that has come to accept aligners as a safe, predictable, and effective means of moving teeth.

19. Since its founding, Align supplied teeth alignment therapy to over 14 million patients through Invisalign®-trained orthodontists and dentists that prescribe Align's advanced Invisalign® system. The Invisalign® system harnesses the knowledge of Invisalign®-trained orthodontists and dentists in more than 100 countries and is constantly improving through artificial intelligence.

20. Align revolutionized orthodontics, transforming the specialty from an analog practice (requiring hands-in-mouth time adjusting wires and brackets) to a digital one (allowing computer-generated precise and efficient movements) with Align's iTero™ intraoral scanner, Invisalign® Outcome Simulator, ClinCheck® software, Invisalign® Doctor Site, My Invisalign™ App and many other technologies. Align develops and markets its products in this District and throughout the U.S.

**B. False Advertising Defendants**

21. Defendant SmileDirectClub, LLC is organized under the laws of Tennessee, with its principal place of business in Nashville, Tennessee. SDC manufactures, markets, sells, and distributes clear aligners in interstate commerce, mailing its aligners directly to consumers throughout the United States. SDC claims to use a teledentistry platform to connect doctors and patients. SmileDirectClub, LLC, is registered with the California Secretary of State to do business in the state.

22. Defendant SDC Financial LLC is a Delaware limited liability corporation that wholly owns and controls SmileDirectClub, LLC.

23. Defendant SmileDirectClub, Inc. is a Delaware corporation, which was formed as part of SDC's initial public offering ("IPO"), through which SmileDirectClub, Inc. purchased a minority financial stake in SDC Financial, LLC. Through the IPO, SmileDirectClub, Inc. and other Defendants raised more than \$1.3 billion through the sale of 58.5 million shares at \$23 per share.

### **C. The Conspiring Defendants for RICO Claims**

24. Defendant David Katzman is the Chief Executive Officer and Chairman of the Board of SDC. David Katzman, as managing partner of Defendant Camelot Venture Group ("Camelot"), provided the initial funding for SDC. On information and belief, David Katzman liquidated shares of SDC stock through the IPO for more than \$190 million, and David Katzman still owns a substantial stake in SDC in his own name, through Camelot, and through various family trusts.

25. Defendant Steven Katzman is David Katzman's brother and the Chief Operating Officer of SDC. On information and belief, Steven Katzman liquidated shares of SDC stock for proceeds of more than \$14 million in the IPO and still owns a substantial stake in SDC through Camelot and various family trusts.

26. Defendant Jordan Katzman is David Katzman's son, is a co-founder of SDC, and serves on its Board of Directors. On information and belief, Jordan Katzman liquidated shares of SDC in the IPO for more than \$150 million and retains a substantial stake in SDC through Camelot and in his own name.

27. Defendant Alexander Fenkell, Jordan Katzman's childhood friend, is a co-founder of SDC, and a member of its Board of Directors. On information and belief, Alex Fenkell liquidated shares of SDC in the IPO for more than \$140 million and retains a substantial stake in SDC through Camelot and various family trusts.

28. Defendant Camelot Venture Group is a private investment group based in Michigan and Florida and controlled by David Katzman. On information and belief, Camelot has the largest financial stake in SDC and is the managing member of the entity that controlled SDC before the IPO. As such, Camelot—through its control as the managing member of SDC, and through its ability to appoint the Katzmans as officers of SDC—controlled SDC for at least a period of years.

29. Defendant Dr. Jeffrey Sulitzer is the Chief Clinical Officer of SDC and the owner and President of Defendant Jeffrey Sulitzer, DMD, Professional Corporation (“Sulitzer PC”).<sup>12</sup> Dr. Sulitzer is licensed to practice dentistry in California, though the California Dental Board has placed his license under probation for allegations of SDC-related misconduct and fraud.<sup>13</sup> Dr. Sulitzer, in his role as Chief Clinical Officer, supposedly manages SDC’s relationships with affiliated dentists and orthodontists. Dr. Sulitzer is personally responsible for many of SDC’s representations to the buying public and to regulatory bodies related to the supposed doctor involvement in SDC’s delivery of clear aligners to consumers.

30. Defendant Sulitzer PC is registered with the California Secretary of State to do business in California, theoretically to engage in the profession of dentistry. The registered address for Sulitzer PC is the same as SDC’s address, 414 Union Street, 8th Floor, Nashville TN 37219. Sulitzer PC ostensibly owns various stores in California operated by SDC, as well as at a minimum one Smile Bus that at least at one point traveled around the state to sell clear aligners to patients.

### JURISDICTION AND VENUE

31. This is an action for false advertising and unfair competition under the Lanham Act, 15 U.S.C. § 1125(a), for wire fraud and mail fraud in violation of the

<sup>12</sup> See generally Second Amended Accusation Before the Dental Board of California Department of Consumer Affairs (Sept. 1, 2021), <https://tinyurl.com/2ccn2acj>.

<sup>13</sup> See California Dental Board, Licensing Details: 51841, <https://search.dca.ca.gov/details/4401/DDS/51841/d260ec1509b39dc102c0aad391b609b3>.



1 Federal Racketeer Influenced and Corrupt Organization (“RICO”) Act, 18 U.S.C.  
2 § 1964(c), for violations of the Arizona RICO statute, Arizona Revised Stat. § 13–  
3 2314.04(A), and for false advertising and unfair competition under California law.

4 32. This Court has subject matter jurisdiction over this action pursuant to  
5 28 U.S.C. §§ 1331 and 1338 because the complaint involves a federal question under  
6 the Lanham Act, 15 U.S.C. § 1125(a)(1)(B), and RICO statutes, 18 U.S.C. § 1964(c).  
7 This Court also has supplemental jurisdiction over state law claims arising out of  
8 the same conduct under 28 U.S.C. § 1367.

9 33. This Court has specific personal jurisdiction over SDC because SDC  
10 regularly and systematically transacts business in, and directed to, the State of  
11 California giving rise to the claims in this action, including its publication of false,  
12 misleading, and fraudulent statements in commercial advertising. Specifically, SDC  
13 advertises, sells, and distributes its aligners throughout the United States, including  
14 in the Northern District of California. SDC and Dr. Sulitzer (who is licensed to  
15 practice in California) committed many of the acts that form the basis of Align’s  
16 claims—including the dissemination of false and misleading ads—in California and  
17 in this District, including via the internet, television commercials, and social media.  
18 At least two of the social media sites that SDC used to disseminate false statements,  
19 Facebook and LinkedIn, are headquartered in this District.

20 34. SDC also has maintained brick-and-mortar storefronts in this District,  
21 and has affiliated with partner-network dental offices in this District, through which  
22 SDC disseminates false and misleading advertising statements, and sells and  
23 distributes its products. SDC opened its first storefront in this District in San  
24 Francisco in 2017 and maintained a store in San Francisco through 2020. SDC’s  
25 current SmileShops in the District include San Mateo, San Jose, and Alameda.

26 35. SDC also opens temporary stores and kiosks in this District  
27 periodically, including in San Rafael, Pleasant Hill, and Vacaville. Upon information  
28

1 and belief, SDC additionally disseminates false and misleading advertising  
2 statements and sells and distributes its products from these Pop-Ups.

3 36. SDC also operated a SmileBus that visited San Francisco, which served  
4 as a mobile location from which SDC disseminated false advertising statements.

5 37. Exercising personal jurisdiction in California is proper both because of  
6 SDC's ongoing and systematic contact with California and the Northern District of  
7 California, including its maintenance of regular places of business in the District,  
8 and because acts giving rise to Align's claims have occurred in the Northern District  
9 of California. SDC has purposefully and voluntarily sent fliers and published ads to  
10 California residents and placed its advertisements into the stream of commerce with  
11 the expectation that its products will be purchased by consumers in this District.

12 38. In addition, from before SDC's founding through December 31, 2020,  
13 *i.e.* for much of the period that SDC has been disseminating its false, misleading,  
14 and fraudulent advertisements (and perpetuating its fraudulent scheme in other  
15 ways), Align was headquartered in San Jose. Accordingly, many of SDC's false  
16 advertisements undermining Invisalign® were directed at this District, and SDC  
17 inflicted much of the financial harm from SDC's wrongdoing on Align in this district.

18 39. Dr. Sulitzer, Sulitzer PC, David Katzman, Stephen Katzman, Jordan  
19 Katzman, and Alex Fenkell (the "Conspiring Defendants") have each (as described  
20 below) intentionally furthered SDC's widespread fraud, including by directing false  
21 statements to California and to this District. In addition, personal jurisdiction over  
22 each of the Defendants is appropriate under 18 U.S.C. § 1965 because the ends of  
23 justice require that each of the Conspiring Defendants be haled into one single court.

24 40. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because a  
25 substantial part of the events giving rise to the claims occurred in this District, a  
26 large portion of SDC's false advertisements were targeted at Align while  
27 headquartered in this District, and defendants are subject to personal jurisdiction.  
28

## INTRADISTRICT ASSIGNMENT

41. For purposes of intradistrict assignment under Civil Local Rules 3-2(c) and 3-5(b), because SDC disseminated its false and fraudulent advertising throughout the District, this action should be assigned on a district-wide basis.

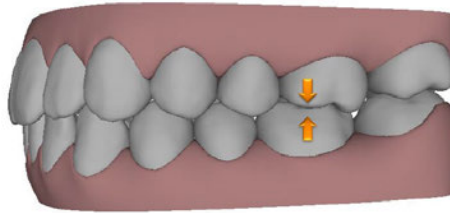
## FACTUAL BACKGROUND

### A. History and Background of Orthodontics

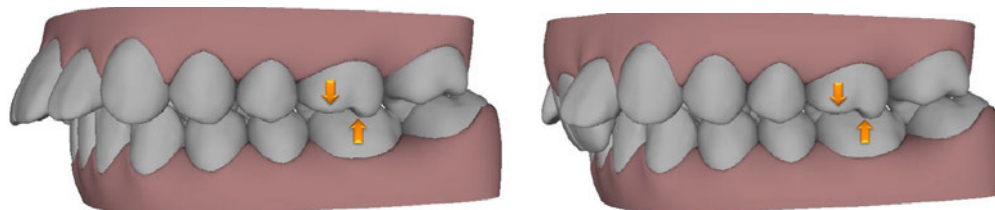
42. Orthodontics is a specialty of dentistry concerned with the prevention and treatment of irregularities of the teeth and jaws, referred to as malocclusion. Orthodontists classify malocclusion in various ways, starting with the physical relationship and distance of patients' upper and lower first molars to each other.

43. Edward Angle (June 1, 1855 – August 11, 1930) is considered the father of modern orthodontics. He created various classifications of malocclusion and standardized appliances for their treatment.

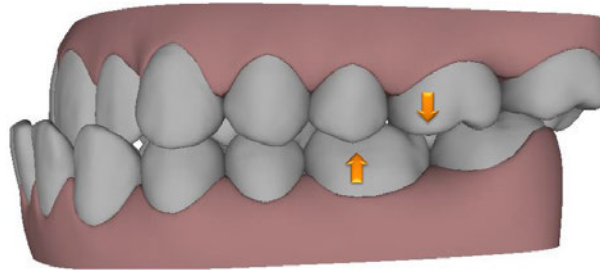
44. A normal bite (class I occlusion) is depicted below, where an individual's first top molar occludes (or impacts) in the buccal groove of the first mandibular (or bottom) molar.



45. Class II malocclusions involve improper tooth alignment where the bottom jaw (the mandible) impacts the upper jaw behind the appropriate resting point. Class II malocclusions typically involve incisors (front teeth) that protrude outward toward the lips (labioversion) or inward toward the tongue (linguoversion).



46. Class III malocclusions involve improper tooth alignment in the opposite front-to-back direction, with the top (maxillary) first molar resting behind the mandibular first molar and frequently involve incisors in a crossbite (where the upper incisors sit behind the lower incisors).



47. In addition, patients' dentition must be characterized and described along other planes of space. Vertical misalignment, for example, can be described as a deep bite (picture on the left) or an open bite (picture on the right).



48. Transverse misalignment and arch-length abnormalities can result in a crossbite (left picture), improper spacing, or crowding of teeth (right picture).

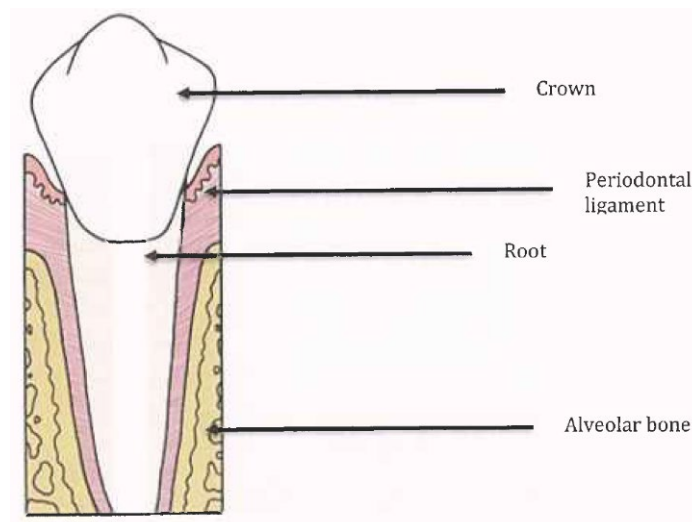


49. When prescribing orthodontic treatment, orthodontists and dentists must consider various factors in addition to alignment, including:

- a. Soft tissue relationships, including the aesthetics of the lips and smile;
- b. Jaw health and balance between the mandible, maxilla, and the teeth, including checking for clicking jaw;
- c. The extent of previous dental or orthodontic treatment;
- d. Whether the teeth are of uniform size or different sizes or unusual anatomy;
- e. Whether the patient is missing permanent teeth, has impacted teeth, or has retained baby teeth abnormally;
- f. The extent of spacing or crowding of teeth;
- g. The degree to which certain teeth have rotated within the dental arch;
- h. Whether the patient has atypical root anatomies, such as bent roots or shortened roots;
- i. Whether the patient has experienced dental trauma;
- j. Whether there are issues arising from the surrounding bone and tissue including from oral cancer; and
- k. Accompanying dental pathologies.

50. Orthodontists for more than a century have moved teeth with various manually adjusted appliances (principally wires-and-bracket braces). Orthodontic appliances move teeth by applying constant gentle forces, including rotational, lateral, and vertical forces, on the teeth over a sufficient period of time.

51. The biomechanical process of moving teeth is mediated by the periodontal ligament. The periodontal ligament is a supporting structure of the tooth that connects the tooth to the bone.



1           52. By applying the optimum force, cellular activity is stimulated without  
2 occluding blood vessels in the periodontal ligament. This allows the bone to resorb on  
3 one side of the tooth while regrowing on the other side (osteoclast and osteoblast).

4           53. If teeth are moved improperly or too quickly, or if patients have  
5 undiagnosed issues (such as cavities or advanced gum disease), serious problems can  
6 result from orthodontic treatment. These problems include gum recession, root  
7 resorption (shrinking of tooth roots), aggravation of bite problems, necrosis of tissue,  
8 and even broken or lost teeth.

9           54. Conversely, proper orthodontic treatment can increase confidence in a  
10 person, improve a person's bite and smile, and preserve tooth and tissue health.  
11 Thus, medical examination and supervision before and during treatment is  
12 important.

13           55. Consistent with standards of care, a doctor evaluating a patient in-  
14 person for orthodontic treatment will generally:

- 15           a. Obtain a medical and dental history of the patient, including an  
16           evaluation of whether a patient has pain in the jaw and neck;
- 17           b. Perform a physical examination of the patient's mouth and facial  
18           structures, including bite, teeth, facial symmetry, jaw movement, joint  
19           function, and speech;
- 20           c. Take photographs and x-rays; and
- 21           d. Perform an examination of the patient's mouth and tissue, and look for  
22           other issues, such as periodontal disease.

23           56. For nearly a century, metal braces were the only predictable way to  
24 straighten teeth. Braces (or fixed appliances) involve attaching a bracket to a tooth  
25 and inserting a wire in the bracket. The wire then applies a constant force on the  
26 tooth to move the tooth into proper alignment. An orthodontist or dentist bends and  
27 shapes the wire as needed to move teeth into final alignment.



**B. Align Invented Moving Teeth with Clear Aligners**

57. In 1997, Align invented a new, powerful tool for dentists and orthodontists, launching the Invisalign® system. The system utilizes a series of custom plastic aligners to transform a patient's bite and the aesthetic appearance of their smile without the traditional wire-and-bracket braces of yesteryear.

58. As opposed to wire-and-bracket braces, Invisalign® clear aligners can be easily removed, allowing consumers to keep brushing, eating, and enjoying their lives as they normally would without the inconvenience and discomfort of traditional braces. The Invisalign® system and aligners, while an elegant and revolutionary solution to crooked teeth, are medical devices that must be prescribed by doctors.



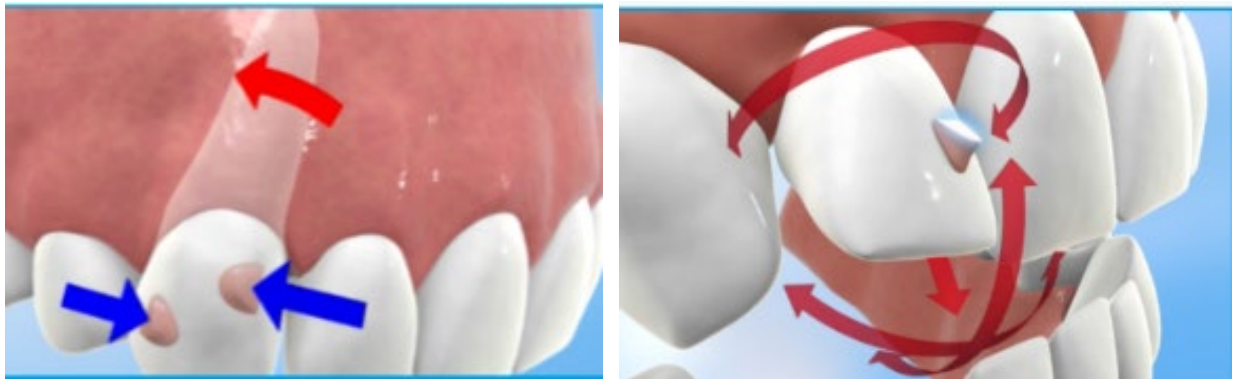
59. To obtain Invisalign® treatment, patients meet with an Invisalign®-trained dentist or orthodontist of their choosing. Through an in-person consultation, and consistent with relevant standards of care (just as a doctor would do with braces) Invisalign®-prescribing doctors will generally take x-rays of the patient's mouth and ensure that they have no significant cavities or periodontal (gum) disease that would preclude treatment with clear aligners. In addition, Invisalign®-prescribing doctors will inspect for shortened or resorbed roots or impacted teeth, probe or measure the patient's gum pockets, and screen for periodontal disease before beginning treatment. Furthermore, the treating doctor may check for loose

1 fillings, crowns, and/or bridges that need to be repaired prior to the use of clear-  
2 aligner therapy.

3 60. Not every patient is a candidate for clear aligners. Certain patients, in  
4 fact, can suffer real harm if they are inappropriately prescribed clear aligners.

5 61. If the patient is a candidate for Invisalign®, the treating dentist or  
6 orthodontist prescribes custom-manufactured clear aligners, for which Align creates  
7 a treatment plan based on the doctor's specification. After the doctor approves the  
8 treatment plan, Align manufactures the clear aligners and the doctor (or doctor's  
9 staff) fits the patient with the clear aligners at the doctor's office. Each aligner is for  
10 a specific stage, or tooth position, of treatment.

11 62. The vast majority of Invisalign® treatment plans (roughly 99% of such  
12 plans) utilize attachments and/or a procedure called interproximal reduction ("IPR"),  
13 which must be conducted in a dentist or orthodontist's office. Through IPR a doctor  
14 shaves a limited amount of enamel in her patient's teeth to create space for  
15 predictable movement. Attachments are small mortar blocks applied to a patient's  
16 tooth to create surfaces to apply forces in optimal directions to prevent teeth from  
17 tipping when moved laterally, among other tooth movements.



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24 63. Because IPR must be performed and attachments must be applied in a  
25 doctor's office (usually by the doctor herself) neither IPR nor attachments may be  
26 utilized in any clear aligner treatment where a patient does not visit their doctor in  
27 person. Doing so would be dangerous.

1           64. Depending on the doctor's professional judgment, the patient may  
2 receive regular in-person check-ups every few weeks to monitor progress and pick up  
3 the next batch of aligners. Based on the patient's unique progress, the doctor may  
4 change the patient's treatment plan as necessary to tailor the patient's care and  
5 based on the doctor's medical discretion.

6           65. Align's relationship with orthodontists and dentists that choose to  
7 prescribe Invisalign® as part of their suite of orthodontic treatment options is at the  
8 heart of Align's business model. Align takes pride in providing these doctors tools  
9 (through the Invisalign® system and Align's iTero® intraoral scanners) to provide  
10 better, more comfortable, more convenient, and more efficient orthodontic care to  
11 their patients. Align has sold the Invisalign® system to doctors for over 20 years, and  
12 in the process has built a strong reputation and acquired substantial goodwill.

13           66. Align has invested more than one billion dollars in innovation,  
14 including developing its state-of-the-art proprietary materials, impression systems,  
15 predictive software, and other research and development. Annually, Align spends  
16 more than \$200 million on research and development to continue providing patients  
17 with the best possible treatment options.

18           67. Align has also invested hundreds of millions of dollars in product  
19 marketing; advertising, including media advertising; sales force compensation;  
20 marketing personnel-related costs; clinical education; and research and  
21 development. Align employs thousands of software engineers, computer-aid design  
22 software designers, and research and development professionals. Align's significant  
23 investments and high standards for quality have yielded considerable goodwill and a  
24 superior reputation in the industry.

25           68. Align's superior technology and reputation in the industry results in  
26 many patients choosing to purchase Invisalign® aligners from doctors. In 2021 alone  
27 Align sold aligners for more than 2.5 million patients.

**C. SDC Created a Direct-to-Consumer Invisalign® Competitor, Promising Consumers Real Doctor-Managed Care**

69. In 2015, SDC copied Align’s invention, creating a direct-to-consumer clear aligner company to compete with the Invisalign® system.

70. SDC patients—who for the most part start their so-called SDC “smile journey” in SDC smile shops or with at-home impression kits (the goopy material that creates 3D models of teeth)—never meet their doctor in person.

71. SDC-interested consumers, however, still want to know that their treatment is directed and supervised by a licensed doctor. Orthodontic treatment involves physically moving teeth through bone and altering bones in patients’ mouths, so it is no wonder that consumers would seek reassurance from SDC that they are receiving safe and effective care from *actual* doctors that direct and monitor their treatment.

72. Consumers’ need for reassurance that they will receive *safe* and *effective* medical care from *real* doctors is manifested by the fact that one Frequently Asked Question on SDC’s website is “Will a real doctor actually lead my treatment?” SDC responds to that question from consumers by promising that “Every aspect of clear aligner treatment with SmileDirectClub . . . is prescribed and managed by an assigned state-licensed dentist or orthodontist.”<sup>14</sup>

**Will a real doctor actually lead my treatment?**

Every aspect of clear aligner treatment with SmileDirectClub—from the creation of the treatment plan through the retention phase—is prescribed and managed by an assigned state-licensed dentist or orthodontist.

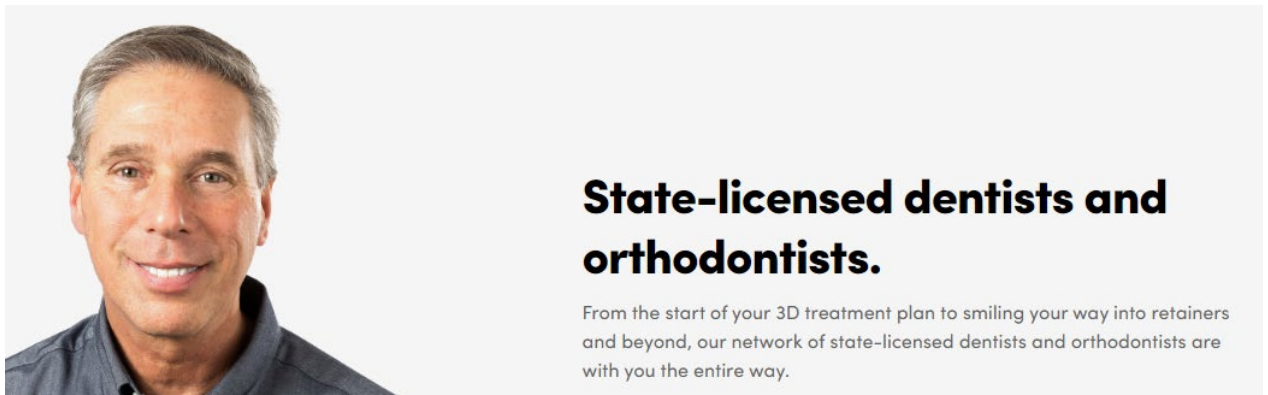
The doctors in SmileDirectClub’s network are held to the same standard of care as at a physical practice. After receiving the 3D images captured at a SmileShop or through an at-home impression kit, the licensed dentist or orthodontist determines the patient’s eligibility for treatment and reviews any necessary X-rays, dental records, and required clearances from the patient’s regular dentist before prescribing a custom treatment plan.

Similar to physical dental practice, SmileDirectClub’s Dental Team is available for support 24/7/365 by phone, email, chat and video to answer any questions and concerns about treatment, and to connect Club Members to their assigned dentist or orthodontist for follow-up care.

<sup>14</sup> [https://smiledirectclub.com/how\\_it\\_works/dentists/](https://smiledirectclub.com/how_it_works/dentists/) (last visited Dec. 1, 2022).

73. In addition, SDC promises that its so-called treating doctors “are held to the same standard of care” and that “**the licensed dentist or orthodontist**” (singular) that reviews a patient’s case “determines the patient’s eligibility for treatment” and reviews any “required clearances from the patient’s regular dentist before prescribing a custom treatment plan.”<sup>15</sup>

74. SDC serially repeats its promise to consumers that they will receive the “same level of care from any treating dentist or orthodontist, with the convenience that comes with online access,” and that SDC treatment is “doctor-prescribed, doctor-directed, and doctor-managed from start to finish,” on its website and in other advertisements.<sup>16</sup> SDC’s chief clinical officer, Dr. Sulitzer, reassures patients that SDC doctors “**are with you the entire way.**”<sup>17</sup>



75. SDC has propagated the lie that SDC’s so-called treating doctors are actively involved in guiding patients’ care through many different media. For example, an SDC television advertisement has represented that “SmileDirectClub is

<sup>15</sup> *Id.* (emphasis added).

<sup>16</sup> *Id.*

<sup>17</sup> [https://smiledirectclub.com/how\\_it\\_works/](https://smiledirectclub.com/how_it_works/) (last visited Dec. 1, 2022) (emphasis added)



1 **heavily guided** by a team of doctors” and emphasizes that SDC customers receive  
2 “doctor-directed care.”<sup>18</sup>

3 76. Another SDC TV advertisement insists that consumers should avoid  
4 paying “more than double” for Invisalign® and instead suggests they get “a smile you  
5 love directed by one of the[] [SDC] doctors.”<sup>19</sup>

6 77. SDC’s Facebook page, moreover, touts one actor’s “favorite thing is that  
7 my treatment plan is being overseen by an actual dentist that I can check in with.”<sup>20</sup>



17 78. And SDC’s YouTube channel features a “Mythbuster” video posted in  
18 May 2022, where Dr. Sulitzer again guarantees not only that a patient’s “treating  
19 doctor evaluates everything,” but that “your treating doctor may ask for additional  
20 documentation from your local dentist to clear you for aligner treatment,” and that  
21 they are “with you every step of the way on your Smile Journey.”<sup>21</sup>

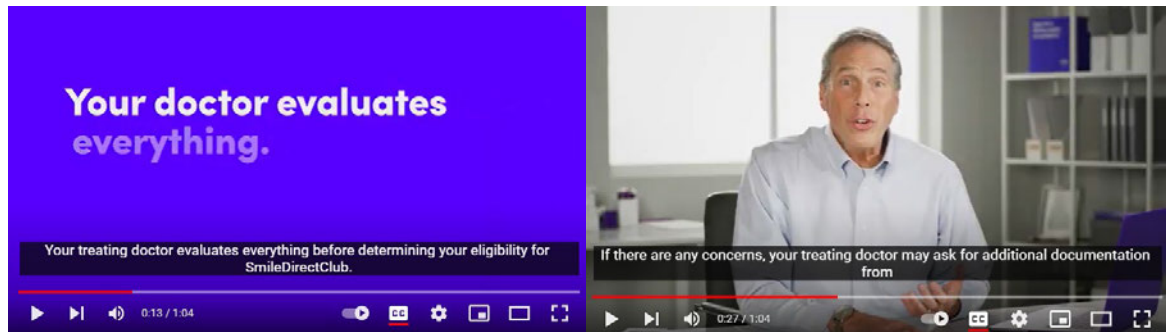
22  
23 <sup>18</sup> This advertisement had been posted at <https://www.ispot.tv/ad/bvGE/smile-direct-club-heavily-guided> (emphasis added), and was accessible as of October 4, 2022, but  
24 appears to have been taken down.

25 <sup>19</sup> <https://www.ispot.tv/ad/OHQT/smile-direct-club-more-than-double> (last visited  
26 Dec. 1, 2022).

27 <sup>20</sup> <https://www.facebook.com/page/406275499508219/search/?q=daugherty> (last  
28 visited Dec. 3, 2022).

<sup>21</sup> [https://www.youtube.com/watch?v=hy\\_KeWQFxR8](https://www.youtube.com/watch?v=hy_KeWQFxR8) (last visited Dec. 1, 2022).





79. What is more, SDC sends emails to prospective SDC consumers comparing SDC treatment to treatment from an in-person Invisalign® doctor. For example, on November 2, 2022, SDC sent a marketing email with the subject line “Save 60% vs. Invisalign. Seriously,” which misleadingly represents that SDC patients receive the “smarter choice” with SDC because they get the same “Doctor-directed care” they would receive with Invisalign® treatment without a “3x markup” and at a much cheaper price.<sup>22</sup>

SmileDirectClub	Invisalign
Doctor-directed care	Doctor-directed care
Lifetime Smile Guarantee™	—
Treatment plan time 4–6 months	Treatment plan lengths vary greatly
No markup	3x markup
Nighttime-only option	—
\$2050 or less than \$89/month	Average \$5200

80. SDC consumers rely on SDC representations that actual dentists and orthodontists comprehensively evaluate their dentition before approving them for clear aligner therapy. For example, one patient who resides in San Francisco and

<sup>22</sup> Ex. 5.

1 visited SDC's Bay Area store reported to the FDA that he or she requested "SDC's  
2 Orthodontist Analysis Report . . . before they charge my credit card" and that SDC  
3 had sent her aligners but "still didn't provide the SDC's orthodontist report." The  
4 patient "presumed [she] could use those aligners as their SDC's orthodontist must  
5 have evaluated and designed them based on [her] needs."<sup>23</sup>

6 81. Another SDC customer reported to the FDA that she purchased SDC  
7 aligners because she "was assured in writing my treatment would be overseen by an  
8 orthodontist in my state of residence."<sup>24</sup>

9 82. SDC's numerous false and misleading advertisements (of which these  
10 are merely examples) are specifically intended to dissuade consumers from going to  
11 real orthodontists and dentists that prescribe Invisalign®.<sup>25</sup> Indeed SDC's website  
12 has long perpetuated SDC's representations about doctor involvement with an "SDC  
13 vs. Invisalign" comparison and continues to include a chart misleading consumers  
14 that they can receive the same type of doctor-directed care from SDC as Invisalign®-  
15 prescribing doctors for cheaper.<sup>26</sup>

16 83. At one time, Align believed that SDC's business model could be  
17 implemented safely if limited to truly simple orthodontic cases and it involved  
18 appropriate medical supervision of patients.<sup>27</sup> Align thus invested in SDC in 2016,  
19 owning a 17% stake that grew to nearly 20% and was liquidated in 2019. During  
20 that investment, Align never learned the extent to which SDC sidelines its doctors  
21 and monopolizes patient care.

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22  
23 <sup>23</sup> Ex. 6, MAUDE Adverse Event Report, No. MW5090617 (Oct. 23, 2019).

24 <sup>24</sup> Ex. 7, MAUDE Adverse Event Report, No. MW5090459 (Oct. 17, 2019).

25 <sup>25</sup> These advertisements not only include website and other written ads but would  
26 include communications through SDC's Partner Network and (on information and  
27 belief) SDC's new offering SDC+.

28 <sup>26</sup> <https://smiledirectclub.com/why-smile-direct-club/> (last visited Dec. 1, 2022).

<sup>27</sup> Indeed, SDC made these representations to Align.

**D. SDC's Advertisements Claiming Doctors Manage and Monitor Care Are False and Knowingly Fraudulent**

84. SDC's promises of doctor involvement in SDC care are false. SDC knows it, too, making SDCs advertising not only false but fraudulent.

85. Myriad public accounts demonstrate that SDC treatment is not in fact guided by doctors with the same level of care as that provided by dentists and orthodontists who prescribe Invisalign® clear aligners, contrary to SDC claims.

86. SDC operates so-called Dental-Service-Organization dental "practices" in various states. At one time, according to public reports, SDC compensated its so-called treating dentists \$50 per evaluated case, and only *if the patient purchased aligners*.<sup>28</sup> As an SDC doctor recently testified in a public Australian hearing, SDC sets the price at which SDC aligners are sold—SDC's professional corporations or so-called treating doctors have no ability to modify the price.<sup>29</sup>

87. As this public report shows, SDC doctors receive compensation based on treatment plan approvals only, and nothing else; SDC's so-called treating doctors receive no further compensation for additional care they may provide throughout a patient's treatment. That means (using a \$50-per-accepted-case fee structure) SDC pays any so-called SDC treating doctor *less than \$50* per evaluated treatment plan because a significant portion of consumers do not purchase aligners after their treatment plans are created and reviewed by the so-called treating doctor.

88. For any competent dentist or orthodontist, \$30-\$40 per patient could not be adequate compensation for completing a comprehensive (albeit digital)

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<sup>28</sup> Ex. 8, American Dental Association Citizen Petition to the FDA at 19 (Apr. 25, 2019); Ex. 9, Q&A with Dr. Ben Burris, (formerly available on orthopundit.com, last visited July 15, 2021).

<sup>29</sup> The Australian Court ruled that SDC "engaged in conduct that was misleading or deceptive." Ex. 10, Order, Fed. Ct. Australia at 1 (Nov. 11, 2022). On information and belief, SDC's practices in Australia mirror their U.S. practices.

1 examination. That fee certainly could not adequately compensate any dentist or  
2 orthodontist for monitoring such patients into the future.

3 89. SDC's compensation structure makes one thing clear—SDC does not  
4 expect its treating doctors to meaningfully review SDC treatment plans, modify SDC  
5 treatment plans with any regularity, or engage with patients in any meaningful (or  
6 frequent) manner. On information and belief, SDC's so-called treating doctors accept  
7 the compensation SDC provides because SDC does not require them to meaningfully  
8 monitor or provide ongoing care to SDC patients. In fact, on information and belief,  
9 SDC's providers expect SDC employees to provide virtually all such services.

10 90. Predictably, since SDC cannot expect doctors receiving less-than-\$50-  
11 per-patient to accept liability for harm caused, an SDC-affiliated doctor in Australia  
12 recently testified that SDC provides insurance for professional negligence and  
13 indemnifies doctors from any claim for professional negligence arising out of any act  
14 or omission related to SDC aligners.

15 91. Public reports also indicate that SDC doctors (as opposed to  
16 Invisalign®-prescribing doctors) “crank out” numerous decisions on treatment plans  
17 and rarely engage with consumers. An anonymous report from “a former SDC store  
18 manager,” for example, said “the company was sending 75 to 100 cases to one  
19 orthodontist’s phone, per day, to ‘crank out’ case decisions.”<sup>30</sup>

20 92. Other reports say that consumers were “never connected, nor given  
21 contact information” for their dentist even “after multiple attempts.”<sup>31</sup> One of SDC's  
22 Australian dentists testified in a public hearing that he has reviewed on average 875  
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24 <sup>30</sup> Ex. 11, Hindenberg Research, SmileDirectClub: Moving Fast and Breaking Things  
25 in People's Mouths (Oct. 4, 2019).

26 <sup>31</sup> NBC News, “Things didn't feel right”: Some SmileDirectClub customers report  
27 problems (Feb. 13, 2020), *available at* [https://www.nbcnews.com/health/health-  
28 news/things-didn-t-feel-right-some-smiledirectclub-customers-report-problems-  
n1134056](https://www.nbcnews.com/health/health-news/things-didn-t-feel-right-some-smiledirectclub-customers-report-problems-n1134056) (last visited Dec. 1, 2022).

1 patient prescriptions per month and he does not have direct contact with the 875  
2 consumers a month that he reviews.

3 93. Several internet message boards include complaints from SDC  
4 customers who tried many times but ultimately could not speak with their doctor,  
5 instead being told “[y]ou can’t reach your dentist, just the [SDC] dental team.”<sup>32</sup>



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11 94. Thus, while SDC has long advertised its (misleading) characterization  
12 that Invisalign®-prescribing doctors charge a 3X markup for Invisalign® clear  
13 aligners,<sup>33</sup> the different compensation structures reflect the different roles of doctors  
14 in SDC’s business model and the added and necessary value of doctor engagement  
15 when patients choose their own independent doctor and purchase Invisalign® clear  
16 aligners from that doctor face-to-face in that doctor’s office. Perhaps one product  
17 could be said to be “marked up” over another comparable one, but that claim is false  
18 and misleading when the consumer is choosing between two totally different things.

19 [REDACTED]  
20 [REDACTED]  
21 [REDACTED]  
22 [REDACTED]  
23 [REDACTED]  
24 [REDACTED]

25 <sup>32</sup> [https://www.reddit.com/r/smiledirectclub/comments/pbl0tl/  
26 how\\_do\\_i\\_speak\\_to\\_my\\_sdc\\_dentist/](https://www.reddit.com/r/smiledirectclub/comments/pbl0tl/how_do_i_speak_to_my_sdc_dentist/)

27 <sup>33</sup> Ex. 1, Capture of “SDC vs. Invisalign” Tab of Smile Direct Club Website,  
28 <https://smiledirectclub.com/why-smile-direct-club/> (Captured Jan. 11, 2022).

Year	Number of Publications
1994	100
1995	80
1996	10
1997	10
1998	10
1999	25
2000	25



1 [REDACTED]  
2 [REDACTED]  
3 [REDACTED]  
4 [REDACTED]  
5 [REDACTED]  
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21 [REDACTED]  
22 [REDACTED]  
23 [REDACTED]  
24 [REDACTED]

25 \_\_\_\_\_

26 39 [REDACTED]

27 40 [REDACTED]

28 41 [https://smiledirectclub.com/how it works/dentists/](https://smiledirectclub.com/how_it_works/dentists/) (last visited Dec. 1, 2022).

1 [REDACTED]  
2 [REDACTED]  
3 [REDACTED]  
4 **E. SDC Perpetuates Its Fraudulent Scheme by Repeating Its False**  
5 **Claims to Regulators, Shareholders, Insurers, and Doctors**

6 104. If consumers knew that SDC's so-called treating doctors did not  
7 actually participate in care or monitor care throughout the life of a patient's  
8 treatment, most of them would not purchase aligners from SDC.

9 105. SDC and the Conspiring Defendants know that they need to perpetuate  
10 the charade of doctor care and monitoring by whatever means necessary. SDC thus  
11 furthers its fraudulent advertising campaign by falsely representing the level of  
12 doctor involvement in care to other entities, such as regulators, shareholders,  
13 insurers, doctors in SDC's "Partner Network," and courts.

14 106. For example, Defendants David Katzman, Steven Katzman, Jordan  
15 Katzman, and Alexander Fenkell signed SDC's S-1 registration statement, required  
16 for SDC to go public. The S-1, under their signatures, represented that SDC's  
17 patients can receive "Doctor-directed remote teledentistry" and that SDC's doctors  
18 use SDC's "SmileCheck . . . to monitor the member's progress" and to participate in  
19 "seamless communication with the member over the course of treatment."<sup>42</sup>

20 107. In addition, SDC's S-1 represented that one doctor, "a state licensed  
21 doctor within our network[,] reviews and approves the member's clinical information  
22 and treatment plan" if *that doctor* thinks "the member is a good candidate for clear  
23 aligners."<sup>43</sup>  
24  
25

26 <sup>42</sup> SDC S-1 at 1, 4, available at [https://investors.smiledirectclub.com/static-](https://investors.smiledirectclub.com/static-files/952c9607-6279-48f1-a5f2-71cda1d36961)  
27 [files/952c9607-6279-48f1-a5f2-71cda1d36961](https://investors.smiledirectclub.com/static-files/952c9607-6279-48f1-a5f2-71cda1d36961) (last visited Dec. 5, 2022).

28 <sup>43</sup> *Id.* at 4.

1           108. And SDC represented to shareholders that “The treating duly licensed  
2 doctor reviews clinical progress through our remote teledentistry platform at least  
3 every 90 days,” “or more frequently, if required.”<sup>44</sup>

4           109. SDC also represented to prospective shareholders that “The doctors in  
5 our network evaluate our members’ progress throughout treatment, and are  
6 available to answer *any questions* should members need additional assistance.”<sup>45</sup>

7           110. SDC has similarly shrouded the truth from (if not outright deceived)  
8 the United States Food and Drug Administration (the “FDA”). In April 2019, the  
9 American Dental Association filed a Citizen Petition with the FDA, alleging that  
10 SDC was placing the public at risk because it was selling clear aligners to consumers  
11 while it “virtually eliminated . . . any substantive participation by a dentist in a  
12 customer’s teeth straightening treatment[.]”<sup>46</sup> Dr. Sulitzer responded to those  
13 allegations in a letter submitted on behalf of SDC that repeated SDC’s  
14 misrepresentations about doctor involvement.<sup>47</sup>

15           111. In that letter, Dr. Sulitzer falsely told the FDA that “the doctors who  
16 contract with SDC are solely responsible for all clinical aspects of their patients’  
17 evaluation, diagnosis, prescription, and treatment.”<sup>48</sup> He also represented that “[a]s  
18 with any other DSO model, the decision whether to proceed with aligner therapy for  
19 a given patient is in the sole discretion of the doctor; SDC has no part in any clinical  
20 or patient care decisions.”<sup>49</sup> He went on: “All aspects of the patients’ clinical care,  
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22           <sup>44</sup> *Id.* at 5-6.

23           <sup>45</sup> *Id.* at 9 (emphasis added).

24           <sup>46</sup> Ex. 8, April 25, 2019 American Dental Association Citizen Petition.

25           <sup>47</sup> Ex. 12, May 10, 2019 SmileDirectClub, LLC Comment to the Citizen Petition Filed  
26 by the American Dental Association.

27           <sup>48</sup> *Id.* at 1.

28           <sup>49</sup> *Id.* at 2

1 from start to finish . . . are solely the responsibility of the doctors[.]”<sup>50</sup> Dr. Sulitzer  
2 also represented that “throughout the treatment period, the doctor is solely  
3 responsible for monitoring his or her patient’s treatment until completion, with  
4 check-ins as often as the doctor chooses but occurring every 90 days, at a  
5 minimum.”<sup>51</sup> And he represented that “[a]t any time during treatment, the doctor  
6 also has the authority and discretion to request or require . . . an in-person office  
7 visit[.]”<sup>52</sup> On information and belief, not one of these SDC representations to the  
8 FDA is true.

9        112. Dr. Sulitzer and other SDC representatives have also appeared before  
10 and corresponded with various states’ dental boards that were concerned with SDC’s  
11 business practices and lack of doctor involvement. In the few public examples of  
12 these exchanges, Dr. Sulitzer and SDC peddled the same mistruths about SDC  
13 doctor involvement with those state regulators. For example, Dr. Sulitzer  
14 untruthfully told the North Dakota State Board of Dental Examiners that “At Smile  
15 Direct Club our patients know who the doctor is” and that his or her “license number  
16 and phone is available. Patients can communicate thru face time, chat, 1-800  
17 number and other ways and therefore patients can get to their doctors.”<sup>53</sup> On  
18 information and belief, Dr. Sulitzer or other SDC representatives would have made  
19 numerous similar representations to other state dental boards.

20        113. SDC has also misrepresented its business model in court filings related  
21 to its disputes with state dental boards. For example, SDC sued members of the  
22 Dental Board of California based on the false premise that “[c]onsumers receive the  
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24 <sup>50</sup> *Id.* at 4-5.

25 <sup>51</sup> *Id.* at 5.

26 <sup>52</sup> *Id.*

27 <sup>53</sup> Ex. 13, North Dakota State Board of Dental Examiners Special Meeting Minutes,  
28 at 4 (June 1, 2022).

1 same level of care from their [SDC] Treating Doctors” as they would from meeting  
 2 face-to-face with a doctor in the doctor’s office.<sup>54</sup> SDC recites its favorite baseless  
 3 refrains in that lawsuit: “The Treating Doctor determines, in their independent  
 4 professional judgment . . . whether the consumer is a candidate for the clear-aligner  
 5 therapy”<sup>55</sup>; that consumers “use SmileCheck for periodic treatment check-in  
 6 appointments” that “can occur more frequently if requested by either the Treating  
 7 Doctor or the consumer”<sup>56</sup>; that the so-called “Treating Doctor maintains sole  
 8 responsibility for all aspects of the consumer’s care throughout the process”;<sup>57</sup> and  
 9 that SDC merely “provides non-clinical, administrative” services to the so-called  
 10 treating doctors.<sup>58</sup> SDC makes nearly identical false statements about its business  
 11 practices in its lawsuit against members of the Georgia Board of Dentistry.<sup>59</sup>

12 114. Further, SDC (on information and belief) has also lied about the extent  
 13 to which SDC doctors are involved in care in order to obtain dental insurance  
 14 coverage for its product. In one public court filing against Delta Dental Plans  
 15 Association, SDC asserted that doctors use SDC’s platform to “monitor the progress  
 16 of treatment, make mid-course corrections and/or refinements as and when needed,  
 17 and guide their patients towards successful and beautiful outcomes. Every clinical  
 18 aspect of the patient’s care is directed by SDC Affiliated Dentists.”<sup>60</sup> An Illinois  
 19 Court of Appeal recently affirmed the dismissal of SDC’s suit against Delta Dental  
 20 Plans Association on the ground that SDC presented no evidence Delta Dental knew

21 <sup>54</sup> Amended Complaint ¶39, *Jeffrey Sulitzer, et al v. Joseph Tippins, et al.*, No. 2:19-  
 22 cv-08902-GW-MAA (C.D. Cal. May 18, 2020), ECF No. 43.

23 <sup>55</sup> *Id.* ¶41.

24 <sup>56</sup> *Id.* ¶44.

25 <sup>57</sup> *Id.*

26 <sup>58</sup> *Id.* ¶3.

27 <sup>59</sup> Proposed Amended Complaint ¶¶22, 24, 37, 38, *SmileDirectClub, LLC v. Tanja D.*  
*Battle, et al.*, No. 1:18-cv-02328-SDG (N.D. Ga. July 29, 2022), ECF No. 148-1.

28 <sup>60</sup> Complaint ¶3, *SmileDirectClub, Inc. v. Delta Dental Plans Association*, No.  
 2020L006973 (Circuit Ct. of Cook County Ill. June 30, 2020).

Delta Dental Plans’ “statements regarding the sufficiency of the supervision licensed dentists provided to SDC’s alignment therapy” were false.<sup>61</sup>

115. On information and belief, SDC has made many such false misrepresentations to dental and health insurance plans, to further SDC’s fraud on the consumer that dentists and orthodontists are heavily engaged in patient care. Patients’ ability to access dental coverage for SDC’s services through certain carriers increases these patients’ (incorrect) perception that they will receive treatment and meaningful supervision from actual licensed dentists and orthodontists.

116. All fifty states outlaw the practice of dentistry without a license. On information and belief, had state dental boards and other regulators known how much SDC displaces the licensed dentists and orthodontists in its system from the clinical decisions about SDC patient care, these regulators would have ended SDC’s fraud on consumers, and/or revoked the licenses of the doctors in SDC’s system that are not supervising the care of their patients.

**F. SDC Perpetuates Its Fraudulent Scheme Through False Representations to Partner-Network Dentists**

117. In addition to lying to consumers and regulators, SDC also lies to doctors that it recruits for its so-called Partner Network and (on information and belief) its forthcoming SDC+ offering to induce such doctors to recommend SDC treatment rather than Invisalign® aligners.

118. Recognizing that some patients want to hear from dentists or orthodontists directly about the type of care they will receive, SDC in January 2020 launched what it called the “SmileDirectClub Partner network.” SDC pays dentists for referrals of patients that have their teeth scanned with an intraoral scanner in

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<sup>61</sup> *SmileDirectClub LLC v. Delta Dental Plans Ass’n*, 2022 IL App (1st) 220208-U, ¶¶ 43-45 (Dec. 8, 2022).



the dentists' chair. The referring dentists, however, do not assume the care of these individuals—the patients remain “under SmileDirectClub’s care.”<sup>62</sup>

119. On information and belief, before dentists and orthodontists agree to join the Partner Network and refer patients from their practices to SDC’s so-called treating doctors’ care, these prospective Partner Network doctors want to know that their patients will receive actual medical supervision.

120. Rather than tell prospective Partner Network doctors the truth, SDC gives false assurances that after their referrals “State-licensed doctors prescribe, direct and manage each treatment plan.”<sup>63</sup>

### Safe and proven.

With SmileDirectClub, your patients receive doctor-directed care from start to finish. You can feel confident recommending SmileDirectClub because:

- State-licensed doctors prescribe, direct, and manage each treatment plan.
- Consistent monitoring of aligner tracking delivers more predictable tooth movement and greater clinical control of outcomes.



121. In addition, SDC publishes accounts to convince doctors to sign up, which promise that “SmileDirectClub affiliated state-licensed doctors . . . monitor treatment from beginning to end.”<sup>64</sup>

122. SDC’s false and misleading representations to prospective Partner-Network doctors constitute false advertising in interstate commerce. SDC indeed explained in its Securities and Exchange Commission Filings that SDC’s Partner Network pitted SDC in head-to-head competition with Align for the loyalties of such

<sup>62</sup> Ex. 14, SmileDirectClub’s Partner Network, *available at* <https://smiledirectclub.com/blog/smiledirectclubs-partner-network/> (last visited Dec. 2, 2022).

<sup>63</sup> <https://smiledirectclub.com/partner-network/> (last visited Dec. 2, 2022).

<sup>64</sup> Ex. 15, Spencer & Spencer, Partner Network Success Stories: Expanding into clear aligners for practice growth.

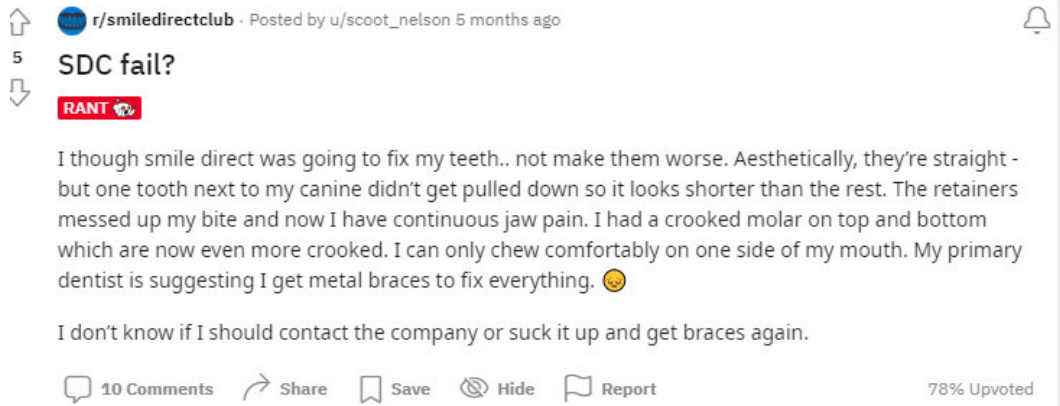
doctors: “With the introduction of our . . . wholesale partner network, we also face competition from more well-established competitors in the traditional orthodontic industry, which requires in-person visits, such as Align Technology, Inc.”<sup>65</sup>

123. If SDC did not misrepresent the care provided by SDC’s so-called treating doctors to Partner-Network practices, more dentists would either prescribe Invisalign® or refer their patients to Invisalign®-prescribing orthodontists.<sup>66</sup>

**G. SDC Perpetuates Its Fraudulent Scheme by Silencing Critics Through Non-Disclosure Agreements and Litigation**

124. SDC covers up the medical consequences SDC treatment can cause by forcing patients that want a refund to sign non-disclosure agreements.

125. Various patients that have had bad experiences with SDC have reported the problems online. For example, one user complained, “I though[t] smile direct was going to fix my teeth.. not make them worse,” and that he or she now has “continuous jaw pain.”<sup>67</sup>



126. These reports would be far more numerous—and far more salient in the public’s mind—if SDC did not utilize non-disclosure agreements to hide the truth. As

<sup>65</sup> SDC 2020 Form 10-K at 10 (<https://investors.smiledirectclub.com/node/7586/html>).

<sup>66</sup> Of course, patients might be referred to orthodontists who prescribe traditional metal braces or to other clear aligner competitors. As the leader in clear aligners, it is fair to assume many, if not most, would end up being prescribed Invisalign®.

<sup>67</sup> [https://www.reddit.com/r/smiledirectclub/comments/tuz2g0/sdc\\_fail/](https://www.reddit.com/r/smiledirectclub/comments/tuz2g0/sdc_fail/)

1 reported by the New York Times, SDC has insisted that patients “sign[] a  
2 nondisclosure provision as part of a general release form” to get a refund.<sup>68</sup>

3 127. To receive a refund, not only must customers refrain from telling others  
4 about the refund, SDC’s form agreement “require[s] them to delete negative social  
5 media comments and reviews,”<sup>69</sup> which limits the public’s access to truthful  
6 experiences with SDC products and distorts publicly available reviews of SDC.

7 128. SDC, moreover, prevents consumers from learning that SDC’s  
8 advertising is false and misleading by threatening doctors with litigation when those  
9 doctors have attempted to dissuade patients from purchasing SDC aligners because  
10 SDC treatment involves a “lack of supervision by trained . . . doctors.”<sup>70</sup> In these  
11 cease and desist letters, SDC lies about SDC’s level of doctor care, claiming (among  
12 other things) that “each and every candidate wishing to use SDC’s teledentistry  
13 platform is evaluated by a [i.e. one] dentist or orthodontist” and that dentist’s “sole  
14 discretion” guides whether the patient is viable for SDC’s products.<sup>71</sup>

15 129. In addition, SDC falsely represents to doctors that “the Treating Doctor  
16 oversees and monitors all clinical aspects of their patient’s care throughout the  
17 course of treatment, including ninety (90) day check-ins to monitor movement of  
18 each individual’s teeth and results.”<sup>72</sup> Indeed, SDC has gone so far as to threaten  
19 doctors with Lanham Act liability based on SDC’s own false narrative and lies about  
20  
21

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22 <sup>68</sup> Griffith & Eavis, *This Company Says It Will Fix Your Smile, It May Shush You if*  
23 *It Doesn’t*, N.Y. Times, Jan. 21, 2020, [https://www.nytimes.com/2020/01/21/](https://www.nytimes.com/2020/01/21/technology/smiledirectclub-smile-nda.html)  
24 [technology/smiledirectclub-smile-nda.html](https://www.nytimes.com/2020/01/21/technology/smiledirectclub-smile-nda.html) (last visited Dec. 2, 2022).

25 <sup>69</sup> *Id.*

26 <sup>70</sup> Ex. 16, Letter from Chase D. Fisher, Senior Litigation Counsel at Smile Direct  
27 Club, to Dr. David Eshom (Mar. 11, 2019).

28 <sup>71</sup> *Id.* at 2.

<sup>72</sup> *Id.*

1 the level of doctor involvement in SDC's business.<sup>73</sup> SDC has thus taken to  
 2 threatening Lanham Act liability to perpetuate the lie on which its business is built.

3 130. On information and belief, SDC must have threatened the American  
 4 Academy of Clear Aligners (AACA) with litigation after that organization published  
 5 an article titled "AACA Strikes Blow Against DIY" in AACA's Summer 2021 issue.  
 6 Subsequently the American Academy of Clear Aligners retracted that statement and  
 7 admitted SDC as a member of the academy.<sup>74</sup> SDC (on information and belief)  
 8 almost certainly threatened the American Academy of Clear Aligners with costly  
 9 litigation to force membership in order to give SDC the veneer of approval from  
 10 respected orthodontists.

11 131. In addition, SDC perpetuates its fraudulent scheme by suing press  
 12 outlets that dare to reveal problems with SDC's model. NBC Nightly News, for  
 13 example, reported (among other things) that one patient "tried but couldn't speak to  
 14 her assigned dentist."<sup>75</sup> Unhappy with the negative coverage, SDC sued for  
 15 defamation, claiming that NBC's report "contained more than 40 false and  
 16 misleading statements about SmileDirectClub" and asserting that "NBC mislead its  
 17 viewers and readers about . . . the involvement of licensed dentists and orthodontists  
 18 in the treatment of patients when using SDC's platform."<sup>76</sup>

19 132. SDC also issued a press release ostensibly to "Respond[] to  
 20 Misrepresentations in the Media," in which it falsely represented that "[j]ust like

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21  
 22 <sup>73</sup> *Id.*

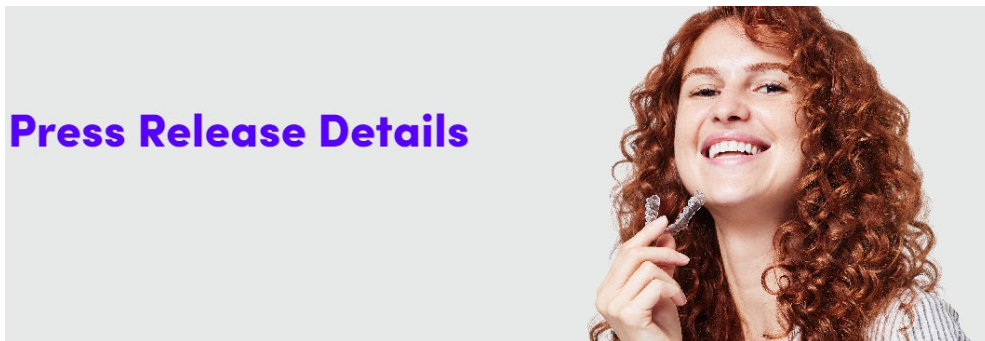
23 <sup>74</sup> <https://www.beckersdental.com/ai-teledentistry/37376-american-academy-of-clear-aligners-retracts-prior-statement-adds-smiledirect-to-organization.html> (last visited  
 24 Dec. 14, 2022).

25 <sup>75</sup> [https://www.youtube.com/watch?v=Ogbo9Ny\\_y-g](https://www.youtube.com/watch?v=Ogbo9Ny_y-g) (last visited Dec. 2, 2022).

26 <sup>76</sup> [https://investors.smiledirectclub.com/news-releases/news-release-  
 27 details/smiledirectclub-files-28-billion-lawsuit-against-nbc-over](https://investors.smiledirectclub.com/news-releases/news-release-details/smiledirectclub-files-28-billion-lawsuit-against-nbc-over) (last visited Dec. 2,  
 28 2022); *see also SmileDirectClub v. NBC Universal Media, LLC*, Complaint, Case No. 20C1054 (Circuit Court for Davidson County Tenn. May 18, 2020).

1 other telemedicine platforms, SmileDirectClub customers interact with their  
 2 treating dentists or orthodontists via our med tech platform. Each patient's  
 3 treatment is supervised by a state licensed dentist or orthodontist from start to  
 4 finish."<sup>77</sup> The trial court allowed SDC to obtain discovery and then dismissed SDC's  
 5 claims under the Tennessee Public Participation Act, on the grounds that SDC could  
 6 not establish the requisite scienter to sue for defamation.<sup>78</sup>

7 133. On information and belief, SDC knew that the statements in NBC's  
 8 reporting were in fact true, and that SDC has long discouraged patients from  
 9 speaking to the licensed dentist or orthodontist theoretically overseeing their  
 10 treatment. But SDC still filed and publicized a lawsuit seeking billions of dollars in  
 11 damages. On information and belief, SDC filed and publicized this baseless lawsuit  
 12 (which has been dismissed by the trial court) as being worth billions of dollars to  
 13 discourage any other news organizations from publicizing negative reports and  
 14 thereby to further its fraudulent scheme.



21 **SmileDirectClub Files \$2.8 Billion Lawsuit Against NBC**  
 22 **Over Defamatory And Error-Filled 'Nightly News' Story**

23 May 18, 2020 at 4:39 PM EDT

24 <sup>77</sup> [https://www.globenewswire.com/news-release/2020/02/14/1985222/0/en/Smile-](https://www.globenewswire.com/news-release/2020/02/14/1985222/0/en/Smile-Direct-Club-Responds-to-Misrepresentations-in-the-Media.html)  
 25 [Direct-Club-Responds-to-Misrepresentations-in-the-Media.html](https://www.globenewswire.com/news-release/2020/02/14/1985222/0/en/Smile-Direct-Club-Responds-to-Misrepresentations-in-the-Media.html) (last visited Dec. 2,  
 26 2022).

26 <sup>78</sup> Order Granting Petition to Dismiss, Case No. 20C1054 (Circuit Court for  
 27 Davidson County Tenn. Jan. 10, 2022).

**H. Absent SDC's False Advertisements Claiming Doctor-Directed Care, Far More Consumers Would Choose Invisalign® Aligners**

134. Consumers care about the level of care they receive from medical professionals and would more likely choose Invisalign® clear aligners from Invisalign®-prescribing doctors if they knew that SDC's so-called treating doctors did not actually provide medically supervised care.

135. While consumers have multiple options in the market for orthodontic treatment, including traditional metal braces, many individuals who want to correct their dentition choose to purchase Invisalign® clear aligners from Invisalign® prescribing doctors because of the convenience of clear aligners and Align's superior technology. There has thus been a direct correlation between consumers duped by SDC's false advertising related to doctor-supervision and lost sales by Align.

136. On information and belief, a significant majority of consumers exploring clear aligners through SDC end up choosing between SDC and purchasing Invisalign® clear aligners from a doctor after an in-person doctors' visit.

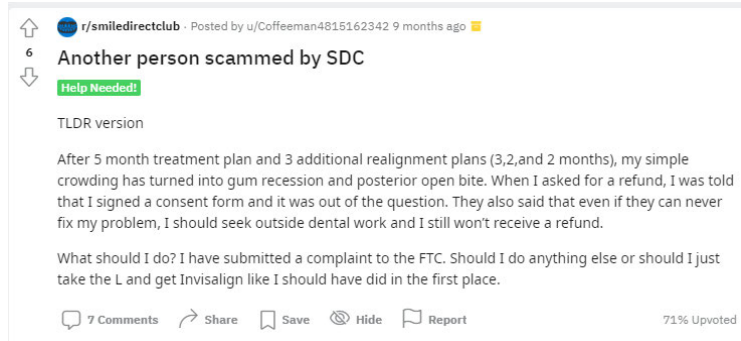
137. SDC's website continues to feature prominently a comparison between SDC aligners and Invisalign®, highlighting the direct competition the companies are engaged in for the hearts and minds of consumers seeking orthodontic treatment.<sup>79</sup>

138. When SDC consumers have poor experiences with SDC aligners, many expressly state that they regret buying aligners from SDC rather than choosing Invisalign® clear aligners. For example, one SDC user on the online forum Reddit complained that his or her "simple crowding has turned into gum recession and posterior open bite" and wondered if she "should [] just . . . get Invisalign® like [she] should have [done] in the first place."<sup>80</sup>

<sup>79</sup> <https://smiledirectclub.com/why-smile-direct-club/> (last visited Dec. 2, 2022)

<sup>80</sup> [https://www.reddit.com/r/smiledirectclub/comments/rcvl8l/another\\_person\\_scammed\\_by\\_sdc/](https://www.reddit.com/r/smiledirectclub/comments/rcvl8l/another_person_scammed_by_sdc/) (last visited Dec. 2, 2022).





139. Various online fora for consumers and patients also make clear that SDC's representations about doctor involvement are important to consumers' decisions whether to pursue treatment with SDC. One SDC user on Reddit, for example, googled "the [SDC] dentist assigned" to his or her case and discovered that dentist had "left his career in dentistry behind to pursue tech startups" and did not otherwise have evidence of a dental practice since 2012.<sup>81</sup>

140. This SDC patient explained that he or she was "feeling a little uneasy with the actual dental oversight in this [SDC] system . . . . It certainly wouldn't feel good to have [their] file be an afterthought for the person that's supposed to make sure it will all turn out okay."<sup>82</sup> This individual is just one example of the large number of SDC customers that would choose to see a real doctor to obtain Invisalign® if they knew SDC's doctors really exercised little to no supervision over patient care in SDC's system. A screenshot of that full online post is below:



<sup>81</sup> [https://www.reddit.com/r/smiledirectclub/comments/an4vvk/feeling\\_a\\_little\\_uneasy\\_about\\_sdcs\\_dentist/](https://www.reddit.com/r/smiledirectclub/comments/an4vvk/feeling_a_little_uneasy_about_sdcs_dentist/) (last visited Dec. 2, 2022)

<sup>82</sup> *Id.*

141. Many doctors have filed complaints with the FDA on behalf of patients who were prescribed SDC aligners despite having preexisting dental conditions that should have disqualified them for SDC treatment. For example, SDC sold one consumer aligners even though she “reported to the employees at Smile Direct Club that she had not seen a dentist in years and that she had a history of TMJ pain.” The doctor she visited to correct the damage done by SDC aligners concluded that “the treatment [SDC] had proposed and began was entirely inappropriate.”<sup>83</sup>

142. Another patient reported to the FDA that SDC sold clear aligners to him despite that he had a broken tooth before starting clear aligner treatment.<sup>84</sup> Such patients should only be prescribed clear aligner treatment after having their preexisting conditions corrected by a real doctor in a real doctor’s office. And those real doctors overwhelmingly would have prescribed Invisalign® clear aligners.

143. A multitude of dissatisfied SDC patients have also filed complaints with the FDA. One customer recounted the “permanent damage” she suffered “due to Smile Direct Club not taking in account the bone around the teeth,” which cost the patient “so much pain and money” that “Invisalign in the first place would have been a cheaper option.”<sup>85</sup> The patient eventually switched to Invisalign® treatment prescribed and monitored by a real doctor, allowing her to compare Invisalign and SDC head-to-head: “Now having Invisalign and seeing what the [follow-up] should be like, I am shocked that I never had a conversation with an [SDC] orthodontist to discuss my treatment which I feel ultimately led to my permanent damage[.]”<sup>86</sup>

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<sup>83</sup> Ex. 17, MAUDE Adverse Event Report, No. MW5090518 (Oct. 21, 2019); *see also* Ex. 18, MAUDE Adverse Event Report, No. MW5090487 (Oct. 18, 2019) (doctor reporting treatment “below the standard of care”).

<sup>84</sup> Ex. 19, MAUDE Adverse Event Report, No. MW5087549 (June 21, 2019).

<sup>85</sup> Ex. 4, MAUDE Adverse Event Report, No. MW5093023 (Feb. 12, 2020).

<sup>86</sup> *Id.*

144. Another SDC customer filed a complaint with the FDA that revealed the truth about SDC doctor involvement (or lack thereof): “These are medical devices and [I] haven’t seen or spoken to a dentist or orthodontist over there at all. The only people who will talk to me are sales. This company needs to be shut down. They are selling a medical device without the patient seeing a real medical professional and its causing harm in multiple ways.”<sup>87</sup>

145. Countless other complaints like these can be found on the Better Business Bureau’s web site (where SDC has earned more than 3,000 consumer complaints in fewer than ten years of operations) and online consumer forums.<sup>88</sup> Many more reports from dissatisfied SDC customers would exist if not for SDC’s policy of forcing dissatisfied patients to delete truthful posts about SDC’s doctor-less treatment before getting refunds.

#### **I. SDC’s False Advertisements Have Harmed and Continue to Harm Align**

146. SDC makes money from its false and fraudulent advertisements that deceive consumers into believing that they receive the same level of doctor supervision with SDC clear aligners as they would when purchasing Invisalign® clear aligner therapy from a dentist or orthodontist in that doctor’s office.

147. Absent SDC’s false and fraudulent advertisements (as well as SDC’s fraudulent scheme designed to hide the truth from consumers), a large portion of consumers that have chosen to purchase clear aligners from SDC would have instead sought in-person medical care from Invisalign®-prescribing doctors and purchased Invisalign® clear aligners from those doctors.

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<sup>87</sup> Ex. 20, MAUDE Adverse Event Report, No. MW5099891 (Mar. 9, 2021).

<sup>88</sup> [https://www.reddit.com/r/smiledirectclub/comments/lx4ou0/sdc\\_caused\\_gum\\_disease\\_and\\_bone\\_loss/](https://www.reddit.com/r/smiledirectclub/comments/lx4ou0/sdc_caused_gum_disease_and_bone_loss/); [https://www.reddit.com/r/smiledirectclub/comments/pnlugt/smile\\_direct\\_club\\_aesthetically\\_fixed\\_my\\_smile/](https://www.reddit.com/r/smiledirectclub/comments/pnlugt/smile_direct_club_aesthetically_fixed_my_smile/) (last visited Dec. 2, 2022).

148. There can be no serious dispute that a substantial portion of the sales gained by SDC's fraudulent doctor claims are sales lost by Align. Indeed, SDC spends tens of millions of dollars in advertising against Align with SDC's false claims of doctor involvement. In July 2021, SDC escalated its false and misleading advertising claims in what SDC refers to as its "Challenger Campaign," which directly targeted at consumers that would otherwise purchase Invisalign®.

149. While in prior years, SDC has described itself as a "disruptor" to the market for teeth straightening, in its Q2 2021 earnings call, SDC told investors that its "Challenger Campaign" is "targeted directly at Invisalign's customer base," further misleading consumers into believing that consumers receive the same level of medical care from SDC's so-called treating doctors as from Invisalign®-prescribing doctors that patients visit in person. SDC's Chief Financial Officer repeated these false and misleading statements in a podcast released on August 18, 2021, promising that SDC offers "the same safe and clinically effective outcome" as Align's Invisalign® system without "going in-person and paying that three times markup."

150. In a podcast released on August 18, 2021, SDC's then-Chief Financial Officer, Kyle Wailes, doubled down on SDC's Challenger Campaign's false and misleading talking points, promising that SDC offers "the same and clinically effective outcome [as Align's Invisalign® system] using . . . our platform and our doctors versus going in-person."<sup>89</sup> In a November 8, 2021 earnings call, SDC made clear that its Challenger Campaign was focused on Invisalign®—"We launched this campaign . . . to target Invisalign® end users with our value proposition."<sup>90</sup>

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<sup>89</sup> Business Breakdowns, Episode 22: *SmileDirectClub: Closing the Gap with Affordability* (released on Aug. 18, 2021), transcript available at <https://joincolossus.com/episodes/380985/wailes-smiledirectclub-closing-the-gap-with-affordability?tab=transcript> (last visited Dec. 2, 2022).

<sup>90</sup> <https://www.fool.com/earnings/call-transcripts/2021/11/08/smiledirectclub-inc-sdc-q3-2021-earnings-call-tran/> (last visited Dec. 2, 2022).

151. SDC continues to advertise directly against Invisalign® based on false doctor-involvement representations, asserting in a current television advertising spot that SDC patients should not pay “more than double” for Invisalign® and instead should “get a smile you love, directed by one of [SDC’s] doctors.”<sup>91</sup>

152. SDC’s fraudulent representations—advertising falsely that SDC’s so-called treating doctors direct patients’ treatment from beginning to end—have caused harm to Align and its business in an amount that will be proved at trial. Monetary damages, however, cannot adequately cure the irreparable harm that SDC’s false advertisements and fraud has caused and continues to cause Align’s business. Only injunctive relief can fully protect Align’s business moving forward. That same injunctive relief will also protect the public from the perils of a company that sells medical devices that move teeth and bone without true doctor supervision.

153. Align created a safe and predictable method for moving teeth with clear aligners. Consumers’ and doctors’ poor experiences with SDC clear aligners has created and has the potential to create a bad reputation for clear aligners among doctors. SDC’s conduct, therefore, if not stopped, will continue to irreparably damage Align’s reputation as a provider of reliable, fast, and effective way of straightening teeth and diminish the goodwill associated with Align’s products.

**J. SDC’s Scheme to Defraud, Perpetuated with the Conspiring Defendants, Amounts to a Pattern and Practice of Fraud**

154. Taken together with the conduct described in the foregoing paragraphs, the following allegations demonstrate that the Conspiring Defendants, through SDC, have engaged in an illegal mail and wire fraud enterprise.

155. SDC claims its mission is to “democratize access to a smile you’ll love by making it affordable and convenient.” Yet SDC in practice is an enterprise designed to maximize clear aligner sales regardless of *how* those sales are achieved.

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<sup>91</sup> [https://www.youtube.com/watch?v=eeCHkrZ\\_sm4](https://www.youtube.com/watch?v=eeCHkrZ_sm4) (last visited Dec. 2, 2022).

156. SDC and the other named defendants have furthered that enterprise through a pattern and practice of mail and wire fraud misleading consumers about the level of doctor supervision they will receive in SDC's system.

**1. SDC is an Enterprise Built on a Pattern and Practice of Racketeering (Mail and Wire Fraud)**

157. SDC, LLC is an enterprise as defined in 18 U.S.C. § 1961(4).

158. SDC was set up as an enterprise to make money for SDC's founders and investors (e.g., among others, David Katzman, Jordan Katzman, Steven Katzman, Alex Fenkell, and Dr. Sulitzer) through the sale of clear aligners.

159. Various individuals and professional corporations have furthered the SDC enterprise through fraud, including David Katzman, Jordan Katzman, Steven Katzman, Alex Fenkell, Dr. Sulitzer, Sulitzer PC, and Camelot Ventures (the "Conspiring Defendants").

160. On information and belief, SDC-affiliated doctors have contracted with various professional corporations throughout the country to which SDC claims to provide "non-clinical dental support organization (DSO) services." On information and belief, many of these professional corporations are also involved in this conspiracy because they know that SDC's representations about doctor involvement are false. Align reserves the right to add them to this complaint once discovery can be obtained as to their identity and level of complicity.

161. The Conspiring Defendants found it easier (and much cheaper) to make money by selling aligners if they did not need to pay SDC-affiliated doctors enough to meaningfully participate in the treatment of SDC patients. As publicly reported, SDC initially decided that it would only pay its so-called treating doctors \$50 per evaluated case, and only then when the consumer purchased aligners.

162. Yet SDC and the Conspiring Defendants—for them to make money and realize gain on their investment—still needed to convince consumers that they would receive medical supervision over their orthodontic care from real doctors. SDC

1 and the Conspiring Defendants thus perpetrated a continuous pattern of  
2 racketeering through mail and wire fraud, including the above-detailed examples of  
3 false and fraudulent representations that doctors exercise all clinical discretion in  
4 SDC's system and that doctors are heavily involved in patient care and monitoring.

5 163. SDC and the Conspiring Defendants' fraud has been ongoing for seven  
6 years and continues to this day, showing a threat of ongoing criminal behavior.

7 164. In addition, to hide the fraudulent activity, the Conspiring Defendants  
8 through SDC (the RICO enterprise) set up sham professional corporations and  
9 contracts with doctors to mask that SDC was providing clinical care to patients.

10 165. The Conspiring Defendants, through SDC and the professional  
11 corporations, perpetuated the fraud by lying to shareholders, regulators, and others  
12 about the level of doctor supervision patients receive. Each of the Conspiring  
13 Defendants furthered SDC's fraudulent false advertising and pattern of fraud  
14 (detailed above) intending that consumers rely on SDC's misrepresentations.

15 166. SDC routinely uses the internet, email, and other interstate  
16 telecommunications networks ("the wires") to perpetuate its fraud on consumers,  
17 intending that these consumers purchase clear aligners while relying on the  
18 representations that they will receive meaningful oversight from their treating  
19 doctor. SDC's pattern and practice of wire fraud is indictable under 18 U.S.C § 1343.

20 167. On information and belief, SDC also uses the United States mail to aid  
21 its scheme and artifice to defraud, by, among other things, shipping SDC clear  
22 aligners to consumers duped by SDC's doctor claims, in violation of 18 U.S.C. § 1341.

23 168. SDC's pattern and practice of mail and wire fraud has directly led to  
24 Align losing Invisalign® clear aligner sales, meaning Align has been massively  
25 injured by reason of SDC's statutory violations.

26 169. Align is in the best position to bring to light and remedy SDC's pattern  
27 and practice of racketeering for many reasons. First, many of SDC's fraudulent  
28



1 statements are directed at misleading would-be Invisalign® customers. Second,  
2 SDC's arbitration and non-disclosure agreements with consumers inhibit these  
3 consumers from forcefully suing SDC (whether in a class action or otherwise). Third,  
4 few if any dental organizations have the scale or wherewithal to challenge SDC's  
5 false and fraudulent representations of doctor involvement when SDC threatens to  
6 sue and impose millions of dollars in legal costs on them.

7 [REDACTED]  
8 [REDACTED]  
9 [REDACTED]  
10 [REDACTED]  
11 [REDACTED]  
12 **K. Each of the Conspiring Defendants Have Intentionally**  
13 **Furthered SDC's Pattern and Practice of Mail and Wire Fraud**

14 [REDACTED]  
15 [REDACTED]  
16 [REDACTED]  
17 [REDACTED]  
18 [REDACTED]  
19 [REDACTED]  
20 [REDACTED]  
21 [REDACTED]  
22 [REDACTED]  
23 [REDACTED]  
24 [REDACTED]  
25 [REDACTED]  
26 [REDACTED]  
27 [REDACTED]  
28 [REDACTED]

# 1. Jeffrey Sulitzer

174. Dr. Sulitzer is the Chief Clinical Officer of SmileDirectClub as well as the President of Sulitzer PC. In these roles, Dr. Sulitzer has participated in the operation and management of SDC as an enterprise and as well as personally to drive SDC's pattern and practice of fraud.

175. Notwithstanding Dr. Sulitzer's intimate knowledge of how the doctor-patient relationship works, Dr. Sulitzer—through SDC—continues to lie to SDC consumers (including through a "Mythbuster" video posted in May 2022), that a patient's "treating doctor evaluates everything" before prescribing treatment. In addition, Dr. Sulitzer falsely represents that each doctor evaluating a patient for treatment "may ask for additional documentation from your local dentist to clear you for aligner treatment," and that they are "with you every step of the way."<sup>92</sup>

176. Dr. Sulitzer knows the truth about SDC's enterprise—it sells aligners through fraudulent advertisements of doctor involvement—and has intentionally participated in the operation and management of the enterprise for his own financial gain (both as a stockholder of SDC and as owner of Sulitzer PC). Dr. Sulitzer has participated in the enterprise and pattern of wire fraud in numerous ways, including lending his own name and credentials as a dentist and the Chief Clinical Officer of SDC to numerous fraudulent misrepresentations set forth above, and in helping architect the byzantine corporate structures (between SDC, individual professional corporations including his own, and SDC-affiliated dentists and orthodontists) that help conceal or obscure those fraudulent misrepresentations.

177. In fact, Dr. Sulitzer recently agreed to probation in order to settle a disciplinary action brought by the California Dental Board that alleged, among other things, that Dr. Sulitzer "[m]isled consumers . . . ; treated patients not of record . . . ; aided and abetted unlicensed practice of dentistry . . . ; [a]ided and abetted dental

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<sup>92</sup> [https://www.youtube.com/watch?v=hy\\_KeWQFxr8](https://www.youtube.com/watch?v=hy_KeWQFxr8) (last visited Dec. 2, 2022).

1 assistants to practice dentistry in a negligent or incompetent manner;  
 2 and . . . [v]iolated the telehealth statute.<sup>93</sup>

## 3                   **2.       Sulitzer PC**

4           178. SDC claims only to provide non-clinical services to professional  
 5 corporations that are owned by “independent doctors,” through which “clinical  
 6 services for clear aligner therapy are rendered to our members.”<sup>94</sup> SDC’s S-1  
 7 recognizes the so-called “independent doctors” provide services through “professional  
 8 corporations (‘PC’s’) managed by [SDC].”<sup>95</sup>

9           179. Sulitzer PC is one of the professional corporations to which SDC claims  
 10 to provide non-clinical services.

11           180. On information and belief, Sulitzer PC has no real, independent  
 12 existence from SDC. In fact, Sulitzer PC’s address is and has been the same as  
 13 SDC’s corporate address, 414 Union Street, 8th Floor, Nashville TN 37219.

14           181. On information and belief, SDC professional corporations, like Sulitzer  
 15 PC, are integral to SDC’s mail-and-wire-fraud scheme because these professional  
 16 corporations give the façade to SDC’s claim that independent doctors—rather than  
 17 SDC itself—manage the treatment given to SDC patients.

18           182. On information and belief, Sulitzer PC (like all similar SDC PCs) exists  
 19 only to create the appearance that SDC complies with laws regarding the corporate  
 20 practice of medicine and to mislead patients into believing that independent doctors  
 21 are overseeing SDC treatment. Sulitzer PC is managing and participating in SDC’s  
 22 enterprise and pattern and practice of fraud by holding itself out as a separate  
 23 professional corporation responsible for the care provided to SDC patients.

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24  
 25 <sup>93</sup> Second Amended Accusation, September 1, 2021, <https://tinyurl.com/2ccn2acj>.

26 <sup>94</sup> SDC S-1 at 126 available at [https://investors.smiledirectclub.com/static-](https://investors.smiledirectclub.com/static-files/952c9607-6279-48f1-a5f2-71cda1d36961)  
 27 [files/952c9607-6279-48f1-a5f2-71cda1d36961](https://investors.smiledirectclub.com/static-files/952c9607-6279-48f1-a5f2-71cda1d36961) (last visited Dec. 5, 2022).

28 <sup>95</sup> *Id.* at F-7.

### 3. David Katzman

183. David Katzman is Chief Executive Officer and Chairman of the Board of SDC. In his role as CEO and Chairman, David Katzman has the ultimate authority for SDC's public representations related to the level of doctor involvement that consumers will receive when they purchase SDC products.

184. David Katzman knows the nature of SDC's enterprise—selling as many aligners as possible, including through fraudulent ads misrepresenting the level of doctor involvement patients are given by SDC's so-called treating doctors.

185. David Katzman has participated in the operation and management of the SDC enterprise, and personally perpetuated SDC's mail and wire fraud, for his own financial gain as one of the largest owners of SDC. Among other things, David Katzman signed and attested to the false statements about doctor supervision in SDC's S-1 set forth above in paragraphs 106 through 109.

186. In addition, David Katzman has issued various statements falsely representing that SDC "rel[ies] on more than 250 doctors in our affiliated network to oversee customer cases from start to finish."<sup>96</sup>

187. On information and belief, David Katzman also directs and approves SDC's fraudulent representations to regulators related to the level of doctor supervision that patients receive when they purchase clear aligners from SDC.

### 4. Steven Katzman

188. Steven Katzman is the Chief Operating Officer of SDC. On information and belief, in that role, Steven Katzman has controlled, directed, and/or furthered SDC's fraudulent advertisements.

189. On information and belief, Steven Katzman as the Chief Operating Officer has oversight and responsibility over SDC's operations, including over how SDC's dental team and customer care teams interface with SDC's doctors.

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<sup>96</sup> <https://www.linkedin.com/pulse/smiledirectclubs-battle-biased-reporting-real-news-david-katzman/?articleId=6634148792990003201> (last visited Dec. 2, 2022).

1           190. Steven Katzman knows the essential nature of SDC's enterprise—  
2 selling as many aligners as possible, including through fraudulent advertisements  
3 misrepresenting the level of doctor involvement patients are given by SDC's so-  
4 called treating doctors. Yet Steven Katzman has neither put an end to SDC's  
5 fraudulent advertising nor adjusted SDC's operations to conform to SDC's  
6 representations regarding doctor supervision.

7           191. Steven Katzman has thus participated in the operation and  
8 management of the enterprise, and personally perpetuated SDC's fraud, for his own  
9 financial gain as one of the owners of SDC. Among other things, Steven Katzman  
10 personally attested to false statements about doctor supervision of SDC patients in  
11 SDC's S-1 set forth above in paragraphs 106 through 109.

## 12                           **5. Jordan Katzman**

13           192. Jordan Katzman is a co-founder of SDC. On information and belief, he  
14 helped create SDC's business model, including SDC's marginalization of the treating  
15 doctor. On information and belief, Jordan Katzman has been directly involved in the  
16 operation and management of the SDC enterprise since its founding.

17           193. Jordan Katzman knows the essential nature of SDC's enterprise—  
18 selling as many aligners as possible, including through fraudulent advertisements  
19 misrepresenting the level of doctor involvement patients are given by SDC's so-  
20 called treating doctors. Yet Jordan Katzman has neither put an end to SDC's  
21 fraudulent advertising nor adjusted SDC's operations to conform to SDC's  
22 representations regarding doctor supervision.

23           194. Jordan Katzman has thus participated in the operation and  
24 management of the enterprise, including SDC's pattern and practice of wire fraud,  
25 for his own financial gain as one of the largest owners of SDC. Among other things,  
26 Jordan Katzman was a signatory to the false statements about doctor supervision of  
27 SDC patients in SDC's S-1 set forth above in paragraphs 106 through 109.

## 6. Alex Fenkell

195. Alex Fenkell is a co-founder of SDC. On information and belief, he helped create SDC's business model, including the marginalization of the role of the treating doctor in SDC's system. On information and belief, Mr. Fenkell has been directly involved in the operation and management of the SDC enterprise since its founding.

196. Alex Fenkell knows the essential nature of SDC's enterprise—selling as many aligners as possible, including through fraudulent advertisements misrepresenting the level of doctor involvement patients are given by SDC's so-called treating doctors. Yet Alex Fenkell has neither put an end to SDC's fraudulent advertising nor adjusted SDC's operations to conform to SDC's representations regarding doctor supervision.

197. Alex Fenkell has thus participated in the operation and management of the enterprise, including SDC's pattern and practice of wire fraud, for his own financial gain as one of the largest owners of SDC. Among other things, Alex Fenkell was a signatory to the false statements about doctor supervision of SDC patients in SDC's S-1 set forth above in paragraphs 106 through 109.

198. In addition, Alex Fenkell has perpetuated SDC's false narrative on news outlets among other places, stating for example that SDC's doctors see patients "one to one" as part of SDC's teledentistry platform.<sup>97</sup>

199. Alex Fenkell's YouTube page also includes a video falsely stating that SDC's at-home treatment is "doctor-directed."<sup>98</sup>



<sup>97</sup> <https://www.youtube.com/watch?v=aLKMq7b53bY> (last visited Dec. 2, 2022).

<sup>98</sup> <https://www.youtube.com/watch?v=BujO6HHzI-I> (last visited Dec. 2, 2022).

## 7. Camelot Venture Group

200. On information and belief, Camelot Venture Group (“Camelot”) provided the initial funding for SDC and remains the largest shareholder of SDC and managing member of the entity that controls SDC.

201. Camelot—through Camelot’s principals David Katzman, Alex Fenkell, Jordan Katzman, and Steve Katzman—knows the essential nature of SDC’s enterprise, which involves selling as many aligners as possible, including through fraudulent advertisements misrepresenting the level of doctor supervision patients receive in SDC’s system.

202. Over time, according to SDC’s S-1, SDC has engaged Camelot Venture Group to provide management services, including the services of David and Steven Katzman. Through this arrangement and through the Camelot principals (David and Steven Katzman) Camelot has participated in the operation and management of the enterprise, including SDC’s pattern and practice of wire fraud, for Camelot’s own financial gain as one of the largest owners of SDC.

### L. Alternative Pleading of Association-in-Fact Enterprise

203. To the extent that SDC itself does not qualify as a relevant enterprise through which the Conspiring Defendants perpetuate their fraudulent scheme under RICO, 18 U.S.C. § 1961(4), then Align pleads in the alternative that SmileDirectClub LLC, SmileDirectClub, Inc., SDC Financial, LLC, and the other Conspiring Defendants have formed an association-in-fact enterprise whose purpose is to sell as many aligners as possible by whatever means necessary, including false and fraudulent advertisements related to doctor involvement in SDC’s system. And SDC together with the Conspiring Defendants perpetuate this scheme through a pattern and practice of wire and mail fraud as set forth above and incorporated herein.



**COUNT I**

**LANHAM ACT FALSE ADVERTISING AND UNFAIR COMPETITION  
AGAINST SMILEDIRECTCLUB LLC, SDC FINANCIAL LLC,  
AND SMILEDIRECTCLUB, INC. (15 U.S.C. § 1125(A))**

204. Align re-alleges and incorporates by reference each allegation contained in paragraphs 1 through 203 of this Complaint as set forth fully herein.

205. Align and SDC both make and sell clear aligners to straighten patients' teeth. Invisalign® aligners and SDC aligners are sold at the same level of the supply chain (to consumers) and are frequently compared by patients seeking orthodontic treatment. SDC perpetuated this comparison by consumers with its false and misleading advertisements.

206. As shown by SDC's advertising against Invisalign® clear aligners and direct comparison of the products, SDC competes with the Invisalign® system even though consumers need to visit a doctor to obtain Invisalign® clear aligners.

207. SDC's false and misleading statements misrepresenting the level of doctor involvement and doctor supervision that SDC's so-called treating doctors provide to SDC patients constitute false advertising, or false commercial speech, in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

208. These false and misleading statements include (but are not limited to) the following:

- a. "Doctor-directed teeth straightening for 60% less than Invisalign, guaranteed for life."
- b. "With SmileDirectClub, you receive the same level of care from any treating dentist or orthodontist, with the convenience that comes with online access."
- c. "Every aspect of clear aligner treatment . . . is prescribed and managed by an assigned state-licensed dentist or orthodontist."
- d. "One of our affiliated doctors . . . directs, and manages your treatment."
- e. "Our network of state-licensed dentists and orthodontists are with you the entire way."

- 1 f. “Smile Direct Club is heavily guided by a team of doctors” and SDC treatment amounts to “doctor-directed care.”
- 2 g. SDC treatment plans are “overseen by an actual dentist.”
- 3 h. An SDC state-licensed doctor reviewing a prospective-patient’s
- 4 case in his or her “sole discretion” will decide whether a patient
- 5 is eligible for SDC treatment or whether additional information
- 6 is needed from the consumer’s local dentist.

7 209. SDC’s claims are false and misleading and misrepresent the nature,  
 8 characteristics, and qualities of the medical care and supervision that SDC patients  
 9 receive as a direct comparison to the medical supervision patients get when they  
 10 receive Invisalign® clear aligners through a doctor of their choice.

11 210. SDC has made these false and misleading claims in commercial  
 12 advertisements regarding SDC’s aligners. SDC disseminated the false and  
 13 misleading statements to the public through commercial advertising and promotion,  
 14 and thus caused them to enter interstate commerce. SDC’s publication,  
 15 republication, distribution, and re-distribution of the false, misleading or deceptive  
 16 statements constitute commercial advertising and promotion under 15 U.S.C.  
 17 § 1125(a).

18 211. SDC disseminated its false and misleading statements regarding doctor  
 19 involvement to convince consumers not to seek in-person medical care from dentists  
 20 and orthodontists that prescribe Invisalign® clear aligners.

21 212. SDC’s false and misleading statements of fact have been, and are  
 22 material, and are likely to continue to induce consumers’ purchasing decisions.  
 23 Specifically, SDC’s false or misleading statements have been and are material to  
 24 consumers in their determination of which teeth-straightening treatment to  
 25 purchase, including causing consumers to purchase SDC clear aligners instead of  
 26 Invisalign® clear aligners from a doctor that would provide the medical supervision  
 27 consumers seek.

1           213. Upon information and belief, SDC's false and misleading claims are  
2 likely to deceive or confuse a substantial segment of the buying public and, in fact,  
3 have actually deceived or confused a substantial segment of the buying public into  
4 buying SDC's products.

5           214. If SDC's customers knew the truth about the minimal—and cursory  
6 nature—of doctor-direction in SDC's business model, a substantial portion of such  
7 customers would have purchased Invisalign® clear aligners in the past or would  
8 purchase Invisalign® clear aligners in the future. As a result, SDC's false and  
9 misleading statements have injured Align's commercial interest in maintaining its  
10 strong reputation and selling its Invisalign® system.

11           215. SDC knows that its statements are false, misleading, or deceptive. At a  
12 minimum, SDC reasonably should know, or failed to investigate so as not to know,  
13 that its statements are false, misleading, or deceptive.

14           216. SDC's acts of false or misleading descriptions of fact, false or  
15 misleading or deceptive representations and unfair competition have proximately  
16 caused Align harm and will continue to proximately and irreparably harm Align,  
17 including irreparably damaging Align's business, reputation, and goodwill.

18           217. SDC's false and misleading misrepresentations related to doctor  
19 involvement in care go to the heart of the differences between Align's business model  
20 and SDCs, since Align sells Invisalign® clear aligners through doctors that patients  
21 choose, while SDC has chosen to create a direct-to-consumer orthodontic company  
22 that all but eliminates the doctor-patient relationship. In addition, SDC's false and  
23 misleading statements have been disseminated in advertisements specifically  
24 designed to dissuade consumers from going to Invisalign®-prescribing doctors for in-  
25 person medical care and to instead purchase SDC clear aligners. As such, SDC's  
26 false statements have proximately caused harm to Align.

1           218. Align stands in the class of plaintiffs protected by the Lanham Act for  
2 these particular false statements, and Align has a right to sue for redress under that  
3 statute. *Lexmark Int'l Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 127-140  
4 (2014).

5           219. This suit from Align is necessary to effectuate Congress' goals of  
6 eliminating false and misleading competitive advertising. Align has been harmed  
7 the most from SDC's false advertising (most of which has been directed at Align)  
8 because no single Invisalign®-prescribing doctor or organization prescribes enough  
9 Invisalign® to have a sufficient economic incentive to sue SDC for its false  
10 advertising.

11           220. Further, individual doctors lack the financial wherewithal or stamina  
12 to withstand litigation against a large, multi-national corporation like SDC that has  
13 a practice of suing industry participants even when SDC's claims are baseless.

14           221. SDC's conduct has caused, and will continue to cause, immediate and  
15 irreparable harm to Align for which there is no adequate remedy at law. Unless  
16 enjoined by this Court, SDC's acts will irreparably injure Align's reputation and  
17 goodwill, erode Align's market share, and harm unsuspecting consumers who insert  
18 a medical device into their mouths falsely believing that it is equivalent to Align's  
19 product. Pursuant to 15 U.S.C. § 1116, Align is entitled to preliminary and  
20 permanent injunctive relief to prevent SDC's continuing acts.

21           222. Pursuant to 15 U.S.C. § 1117, Align is entitled to damages for SDC's  
22 Lanham Act violations, an accounting of profits made by SDC on sales of its clear  
23 aligners, as well as recovery of the costs of this action.

24           223. SDC's acts are willful, wanton and calculated to deceive, and are  
25 undertaken in bad faith, making this an exceptional case entitling Align to recover  
26 reasonable attorneys' fees pursuant to 15 U.S.C. § 1117.

**COUNT II**  
**CALIFORNIA FALSE ADVERTISING AGAINST SMILEDIRECTCLUB LLC,**  
**SDC FINANCIAL LLC, AND SMILEDIRECTCLUB, INC.**  
**(BUSINESS & PROFESSIONS CODE § 17500, *ET SEQ.*)**

224. Align re-alleges and incorporates by reference each allegation contained in paragraphs 1 through 223 of this Complaint as set forth fully herein.

225. On information and belief, SDC has disseminated or caused to be disseminated commercial advertisements, including over the internet, from this state, throughout this state and other states.

226. These advertisements involve false and misleading statements of fact by SDC about its own product, including false representations of doctor involvement.

227. SDC knew or should have known through the exercise of reasonable care that these statements were untrue or misleading.

228. SDC's false advertisements related to doctor involvement are material to consumers deciding on clear aligner treatment.

229. SDC's false representations are likely deceive a reasonable consumer and have actually deceived a substantial segment of clear aligner consumers.

230. Align has suffered injury in fact and has lost sales and money and is likely to continue to be injured as a direct and proximate result of SDC's violation of this chapter.

231. SDC's conduct in violation of Business and Professions Code § 17500 has caused, and will continue to cause, immediate and irreparable harm to Align for which there is no adequate remedy at law.

232. Unless enjoined by this Court, SDC's acts will irreparably injure Align's reputation and goodwill, erode Align's market share, and harm unsuspecting consumers who insert a medical device into their mouths falsely believing that it is equivalent to Align's product.

**COUNT III****CALIFORNIA UNFAIR COMPETITION AGAINST SMILEDIRECTCLUB LLC,  
SDC FINANCIAL LLC, AND SMILEDIRECTCLUB, INC.  
(BUSINESS & PROFESSIONS CODE § 17200, *ET SEQ.*)**

233. Align re-alleges and incorporates by reference each allegation contained in paragraphs 1 through 232 of this Complaint as set forth fully herein.

234. SDC's unlawful and/or fraudulent business acts and practices, as described herein and previously in the complaint, violate Section 17200 of California's Unfair Competition Law.

235. Through advertisements, SDC widely disseminated false and misleading statements about its doctor involvement.

236. SDC knew or should have known through the exercise of reasonable care that these statements were untrue or misleading.

237. SDC's false statements about doctor involvement are likely to deceive reasonable consumers and have deceived a large segment of clear aligner consumers.

238. SDC's false advertising violates other California laws, including Cal. Bus. & Prof. Code § 17500, *et seq.*, and federal law, including the Lanham Act (15 U.S.C. § 1125(a)).

239. Align has suffered injury in fact and has lost sales and money and is likely to continue to be injured as a direct result of SDC's unfair competition.

**COUNT IV****PATTERN AND PRACTICE OF WIRE AND MAIL FRAUD IN VIOLATION  
OF CIVIL RICO AGAINST THE CONSPIRING DEFENDANTS  
(18 U.S.C. § 1964(C))**

240. Align re-alleges and incorporates by reference each allegation contained in paragraphs 1 through 239 of this Complaint as set forth fully herein.

241. SDC constitutes an enterprise that was created to and is operated to sell as many aligners as possible, regardless of means and regardless of the medical suitability of the consumers, to enrich the Conspiring Defendants through sales of aligners and by increasing the perceived value of their shares of SDC. Alternatively,

1 SDC and the Conspiring Defendants have formed an association-in-fact enterprise  
2 designed to sell as many aligners as possible through fraudulent means.

3 242. The Conspiring Defendants conducted and participated in SDC's affairs  
4 through a pattern and practice of racketeering through multiple acts of wire fraud,  
5 in violation of 18 U.S.C. §§ 1343, 1962, by using the wires to execute a scheme to  
6 defraud consumers with the specific intent to defraud consumers about doctor  
7 involvement, through the knowingly fraudulent statements detailed in this  
8 complaint (among others).

9 243. On information and belief, the Conspiring Defendants conducted and  
10 participated in SDC's affairs through a pattern and practice of racketeering through  
11 multiple acts of mail fraud, in violation of 18 U.S.C. §§ 1343, 1962, by using the mail  
12 to execute a scheme to defraud consumers with the specific intent to defraud  
13 consumers about doctor involvement.

14 244. The Conspiring Defendants have directly and indirectly conducted and  
15 participated in SDC's false advertisements, fraudulently representing that SDC's so-  
16 called treating doctors have autonomy in clinical decisions and monitor care from  
17 start to finish. This constitutes a scheme or artifice to defraud for financial gain,  
18 reasonably calculated to deceive persons of ordinary prudence and comprehension.

19 245. Each of the Conspiring Defendants knowingly and intentionally  
20 participated in SDC's scheme to defraud consumers related to the lack of doctor  
21 involvement in SDC's business model.

22 246. Each of the Conspiring Defendants participated in the management  
23 and operation of SDC's illicit enterprise while knowing the essence of the enterprise.

24 247. These false statements and advertisements, examples of which are  
25 detailed in this complaint, constitute a pattern of racketeering activity pursuant to  
26 18 U.S.C. § 1961(5). These related advertisements set forth a consistent and false  
27 message that SDC's business model is predicated on doctor involvement.  
28





1 potential and actual consumers that SDC's clear aligner treatment involved doctor  
2 participation and oversight.

3 256. These repeated and related false statements about doctor involvement,  
4 many of which are detailed in this complaint, are predicate acts that continuously  
5 span a period of over seven years and are ongoing today, posing a threat of continued  
6 unlawful activity.

7 257. Align, which is now headquartered in Arizona, has been injured and  
8 continues to be injured as a direct and proximate result of defendants' racketeering  
9 activities and violations of A.R.S. § 13-2310(A). SDC's racketeering activities have  
10 directly targeted Align and consumers who would have otherwise purchased  
11 Invisalign® aligners and have thus directly and foreseeably caused Align to lose  
12 sales.

### 13 JURY DEMAND

14 258. Pursuant to Federal Rule of Civil Procedure 38(b), Align hereby  
15 demands a trial by jury as to all issues raised in this Complaint.

### 16 PRAYER FOR RELIEF

17 **WHEREFORE**, Align prays for judgment as follows:

18 259. That judgment be entered in favor of Align and against Defendant SDC  
19 on Counts I through III of this Complaint;

20 260. That judgment be entered in favor of Align and against the Conspiring  
21 Defendants on Counts IV and V of this Complaint;

22 261. For entry of an order and judgment in the aggregate amount of Align's  
23 actual damages, including but not limited to Align's costs of corrective advertising,  
24 and/or restitution or disgorgement of all revenues, earnings, profits, compensation  
25 and benefits that may have been obtained by SDC and the Conspiring Defendants as  
26 a result of their unlawful, unfair and/or fraudulent business acts or practices;

1           262. For entry of orders and judgment both preliminarily and permanently  
 2 enjoining SDC, its agents, servants, employees, attorneys, successors and assigns,  
 3 and all others in active concert or participation with them, from falsely or  
 4 misleadingly advertising or promoting aligners by falsely describing the nature of  
 5 doctor involvement in SDC's business, including, without limitation, the following  
 6 advertisements:

- 7           a. That SDC treatment constitutes "Doctor-directed teeth  
 8 straightening."
- 9           b. "With SmileDirectClub, you receive the same level of care from  
 10 any treating dentist or orthodontist, with the convenience that  
 comes with online access."
- 11           c. "Every aspect of clear aligner treatment . . . is prescribed and  
 12 managed by an assigned state-licensed dentist or orthodontist."
- 13           d. "One of our affiliated doctors . . . directs, and manages your  
 treatment."
- 14           e. "Our network of state-licensed dentists and orthodontists are  
 15 with you the entire way."
- 16           f. "Smile Direct Club is heavily guided by a team of doctors" and  
 SDC treatment amounts to "doctor-directed care."
- 17           g. SDC treatment plans are "overseen by an actual dentist."
- 18           h. An SDC state-licensed doctor reviewing a prospective-patient's  
 19 case in his or her "sole discretion" will decide whether a patient  
 20 is eligible for SDC treatment or whether additional information  
 is needed from the consumer's local dentist.
- 21           i. That SDC treatment constitutes "doctor-directed teeth  
 straightening for 60% less than Invisalign."

22           263. For entry of an order and judgment requiring that SDC destroy all  
 23 deceptive advertising materials and undertake corrective measures to rectify any  
 24 erroneous impression consumers may have derived concerning the level of doctor  
 25 involvement in SDC's business;

26           264. For entry of an order and judgment that SDC has violated the  
 27 provisions of 15 U.S.C. § 1125(a) by unfairly competing against Align and by using  
 28

1 false or misleading descriptions or representations of fact that misrepresent the  
2 nature, quality, and characteristics the level of supervision SDC doctors provide in  
3 order to compare SDC aligners with the medical oversight provided by Invisalign®-  
4 prescribing doctors;

5       265. For entry of an order and judgment directing SDC, pursuant to 15  
6 U.S.C. § 1116(a), to file with this Court and serve upon Align within thirty (30) days  
7 after entry of the injunction, a report in writing under oath setting forth in detail the  
8 manner and form in which Defendant SDC has complied with the terms of the  
9 injunction;

10       266. For entry of an order for costs and attorney fees as authorized by law,  
11 including (but not limited to) pursuant to 15 U.S.C. § 1117(a); 18 U.S.C. § 1964(c);  
12 A.R.S. § 13-2314.04;

13       267. For entry of an order for enhanced damages pursuant to 15 U.S.C.  
14 § 1117(a); 18 U.S.C. § 1964(c); A.R.S. § 13-2314.04;

15       268. For entry of an order and judgment awarding prejudgment interest on  
16 all amounts awarded; and

17       269. For entry of an order and judgment awarding such other relief as the  
18 Court deems just, equitable and proper.

1 DATED: Jan. 3, 2023

Respectfully submitted,

2 /s/ Adam M. Rapp  
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*\*pro hac vice forthcoming*

*Attorneys for Plaintiff, Align Technology, Inc.*

# Exhibit 1

Document title: Why Smile Direct Club Aligners | SmileDirectClub

Capture URL: <https://smiledirectclub.com/why-smile-direct-club/>

Page loaded at (UTC): Tue, 11 Jan 2022 12:28:27 GMT

Capture timestamp (UTC): Tue, 11 Jan 2022 12:29:07 GMT

Capture tool: v7.13.2

Collection server IP: 34.230.137.168

Browser engine: Chrome/77.0.3865.120

Operating system: Microsoft Windows NT 10.0.17763.0 (10.0.17763.0)

PDF length: 5

Capture ID: 6054d830-9b4c-4854-96d0-b504e4cb56d1

User: bartlit-kgovertsen





SDC vs Invisalign How It Works Results Pricing Insurance SDC Teens Locations [Free scan](#) Accessories

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[Get Started](#)

#### WHY SMILEDIRECTCLUB?

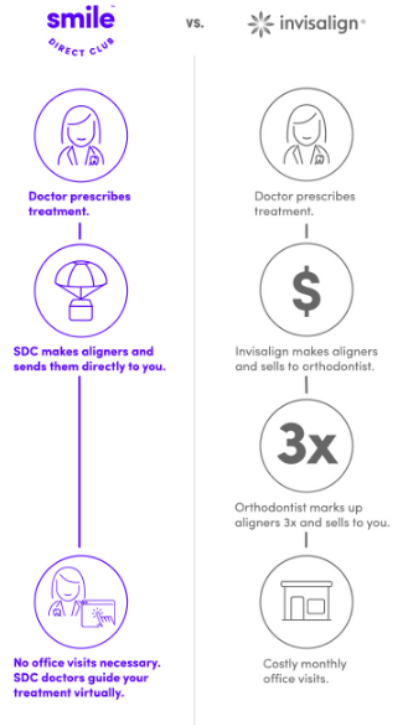
## Doctor-directed teeth straightening for 60% less than Invisalign\*, guaranteed for life.<sup>3</sup>

Don't pay \$5200 for Invisalign.<sup>4</sup> SmileDirectClub offers a total end-to-end teledentistry solution without the 3x markup.<sup>1</sup>

- One of our affiliated doctors prescribes, directs, and manages your treatment.
- We help guide your treatment with regular virtual Smile Check-ins™, including 24/7/365 access to our dental care team.
- You can get a new smile in as little as 4-6 months,<sup>6</sup> not years.
- All for less than \$89 per month<sup>2</sup> with guaranteed financing approval.

A premium experience. Unmatched value. And the results you want backed by our Lifetime Smile Guarantee™.<sup>3</sup> Choose smile.

[AM I A CANDIDATE?](#)



## Compare your options.

As the world's largest direct clear aligner company, SmileDirectClub offers advantages others can't.

	<b>smile</b> DIRECT CLUB	Invisalign	Traditional Braces
Doctor-directed care	✓	✓	✓
Lifetime Smile Guarantee™ ⓘ	✓		
Cost <sup>4</sup>	<b>\$1950 or less than \$89/month<sup>2</sup></b>	Average \$5200	Average \$5600
Over 1.5 million satisfied customers	✓	✓	✓
24/7 access to a dedicated dental team ⓘ	✓		
Made in the USA	✓		Varies
Regular virtual Smile Check-ins™ by your prescribing doctor ⓘ	✓		
Price markup <sup>1</sup> (from orthodontist to consumer) ⓘ	<b>No markup</b>	3x	8x



Sign In



Get Started

AM I A CANDIDATE?

Price markup <sup>1</sup> (from orthodontist to consumer) ⓘ	No markup	3x	8x
Financing with 100% approval ⓘ	Yes, less than \$3/day <sup>2</sup>		
Estimated Insurance coverage <sup>5</sup> ⓘ	50%	29%	27%
Estimated out-of-pocket costs after insurance coverage <sup>5</sup> ⓘ	\$975 or less	\$3700	\$4100
30-Day Money-Back Promise ⓘ	✓		
Removable for sports, eating, drinking, and flossing	✓	✓	
Glued attachments and buttons ⓘ	No	✓	✓
Teeth shaving ⓘ	No	✓	✓
Comfort Sense <sup>TM</sup> ⓘ	✓		
Smart Sculpt <sup>TM</sup> ⓘ	✓		
Treatment plan length	4-6 months <sup>6</sup>	Varies greatly	Varies greatly
Discreet ⓘ	✓	✓	
Ways to get started ⓘ	From home, SmileShop, dentist's office	Dentist or orthodontist	Orthodontist
Mandatory in-office visits ⓘ	No	✓	✓
Nighttime-only option ⓘ	✓		
Cost of retainers <sup>7</sup>	\$99	Avg. \$313	Avg. \$305
Accepts HSA, FSA, CareCredit	✓	✓	✓
Premium teeth whitening included	✓		

Get started

## Choose smart. Choose smile.

Learn why SmileDirectClub is your best value.

**Credibility:** Delivering better treatment and results through advanced teledentistry. +

**Certainty:** A smile you'll love, for life. +

**Comfort Sense <sup>TM</sup>:** Innovations that make our aligners look and feel better than ever. +



**Convenience:** A treatment plan that fits your lifestyle. +

**Cost:** The smile of your dreams is within your reach. +

## Ready. Set. Smile.

Impression kit or scan, choose how you want to start your journey.

Get started



## We've got your whole smile covered.

Let us help you make the most of your smile every day - in every way.

### choose straighter.



Order an impression kit or book a scan to start your doctor-directed clear aligner treatment today.

Get started

### choose brighter.



Whiten your teeth up to 9 shades with **bright on®** premium teeth whitening.<sup>9</sup>

Shop whitening

### choose cleaner.



Our electric toothbrush cleans 50% better than a manual.<sup>10</sup>

Shop oral care



Get started

Shop whitening

Shop oral care



## Learn More

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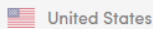
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<sup>1</sup> "3x markup" claim is based on the average cost of Invisalign aligners charged to the dentist or orthodontist by Align Technology, Inc., as compared to the average total fees (including diagnostics and in-person exams) charged to the consumer by the dentist or orthodontist for treatment of mild-to-moderate malocclusion with Invisalign, as reported in a 2021 national survey of practicing dentists and orthodontists.

<sup>2</sup> SmilePay™ is \$89/month for 24 months with \$250 deposit (\$2386). APR varies. See [SmileDirectClub.com/Pricing/APR-Financing](#) for financing details for your state.

<sup>3</sup> SmileDirectClub treatment is backed by our Lifetime Smile Guarantee™. Terms and conditions apply. See [SmileDirectClub.com/guarantee](#) for details.

<sup>4</sup> "Less than \$3/day" claim is based on SmilePay™ monthly payments divided by 30 days. SmilePay is \$89/month for 24 months with \$250 deposit (\$2386). APR varies. See [SmileDirectClub.com/Pricing/APR-Financing](#) for financing details for your state.

<sup>5</sup> Based on the average total fees for treatment of mild-to-moderate malocclusion less the median insurance maximum coverage provided by 9 of the 10 leading insurers in the United States. Data on file at SmileDirectClub.

<sup>6</sup> "8x markup" claim is based on the average cost of traditional braces charged to the orthodontist by the manufacturer, as compared to the average total fees (including diagnostics and in-person exams) charged to the consumer by the orthodontist for treatment of mild-to-moderate malocclusion with traditional braces, as reported in a national survey of practicing orthodontists.

<sup>7</sup> Based on the average retail value of retainers when purchased independent of treatment. Data on file at SmileDirectClub.

<sup>8</sup> "As little as 60 days" claim is based on survey results with customers who were in treatment with SmileDirectClub 22 hour wear clear aligners where 80% said they saw movement within the first 60 days.

<sup>9</sup> "9 shades whiter" claim is based on average results after 1 week when used as directed. Results may vary. Based on internal study, data on file.

<sup>10</sup> "Cleans 50% better" claim is based on a comparison to a standard round filament brush. Results from independent study, data on file.

<sup>11</sup> "\$5200 average cost of Invisalign" claim is based on average total fees (including diagnostics and in-person exams) for treatment of mild-to-moderate malocclusion with Invisalign as reported in a 2021 national survey of practicing dentists and orthodontists.

<sup>12</sup> Cost of SmileDirectClub aligners based on Single Pay. Costs of Invisalign and traditional braces based on average total fees (including diagnostics and in-person exams) for treatment of mild-to-moderate malocclusion with Invisalign or braces as reported in national surveys of practicing dentists and orthodontists. Price comparison does not include additional costs, such as retainers. As treatment is highly individualized, results may not be the same.

\* "60% less than Invisalign" claim is based on Single Pay vs. average fees (including diagnostics and in-person exams) for treatment of mild-to-moderate malocclusion with Invisalign as reported in a national survey of practicing dentists and orthodontists. Price comparison does not include additional costs, such as retainers. As treatment is highly individualized, results may not be the same.

\*\* "60% less than braces" claim is based on Single Pay vs. average fees (including diagnostics and in-person exams) for treatment of mild-to-moderate malocclusion with braces as reported in a survey of orthodontists. Price comparison does not include additional costs, such as retainers. As treatment is highly individualized, results may not be the same.

\*\*\* "4-6 months" claim is based on the number of 22 hour wear customer orders (approx. 95%) with treatment plans that are 4, 5, or 6 months.



# Exhibit 2

## SUS VOLUNTARY EVENT REPORT (FOI for Manufacturers)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5090525	SMILE DIRECT CLUB / ALIGN TECHNOLOGY, INC.	21-OCT-2019	22-OCT-2019 12:00:00.00

## Event Information

Event Date (B3):	13-DEC-2018	Event Report Type (H1):	Serious Injury	Adverse Event (B1):	Y
Report Date (B4):	18-OCT-2019	Event Outcome (B2):	Other Serious (Important Medical Event)		
		Reporter Occupation (G3):	DENTIST		
Problem (B1):	Y				

## Device Information - 1

Product Code (E2b):	ALIGNER, SEQUENTIAL (NXC)		
Brand (E1):	SMILE DIRECT CLUB		
Device Type (E2):	ALIGNER, SEQUENTIAL		
Model #(E4):		Other # (E4):	
Catalog #(E4):		Lot # (E4):	
		Implant Date (E6):	
		Explant Date (E7):	
Expiration Date (E4):		Single Use (E8):	I
Device Available for Evaluation (C):	Y	Date Device Returned to Mfr (C):	

## Mfr Contact Name and Address (E3)

E3 ? Mfr Name:	SMILE DIRECT CLUB / ALIGN TECHNOLOGY, INC.
Address (E3):	NASHVILLE, TN 37219 UNITED STATES

## SUS VOLUNTARY EVENT REPORT (FOI for Manufacturers)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Description****(B5):****Date FDA received:** 21-OCT-2019

Voluntary 22-OCT-2019 12:00:00.00:

THIS PT UNDERWENT ORTHODONTIC THERAPY WITH (B)(6). IT IS MY ASSESSMENT AS AN ORTHODONTIC PROFESSIONAL THAT A MEDICAL DEVICE IS BEING PRESCRIBED TO STRAIGHTEN HER TEETH WITHOUT BEING UNDER THE SUPERVISION OF A TRAINED DENTIST / ORTHODONTIST. SHE WAS CHARGED \$2000 FOR A SERVICE THAT LEFT HER TEETH CROCKED, THE HEIGHTS OF HER FRONT TEETH ARE COMPLETELY UNEVEN, THE BACK TEETH DO NOT COME TOGETHER PROPERLY AND SEVERAL OF THOSE TEETH ARE INTERFERING WITH EACH OTHER, AND THE SUPPOSED "DOCTOR" DIAGNOSING AND ASSISTING WITH THIS CASE LEFT 2 UNERUPTED PERMANENT TEETH UNDER THE GUMLINES AND EXISTING BABY TEETH ON A (B)(6) Y/O GIRL. (B)(6) ALSO FAILED TO ALERT THE PT THAT SHE IS ALSO MISSING 2 PERMANENT TEETH, AND IN ONE INSTANCE, THE REMAINING BABY TOOTH IS SUBMERGING DOWN BELOW THE LEVEL OF ALL THE ADJACENT TEETH, CAUSING THE BITE TO BE EVEN WORSE. ALL OF THIS IS VISIBLE IN THE PHOTOS AND X-RAYS PROVIDED. A FIRST YEAR DENTAL STUDENT WOULD KNOW TO NOT LEAVE PERMANENT TEETH IN THE JAWBONE WITHOUT OFFERING TREATMENT OPTIONS, AND THEY WOULD ALSO KNOW THAT AT AGE (B)(6), ALL BABY TEETH SHOULD HAVE FALLEN OUT, THUS EXTRACTIONS OF ALL BUT 2 PRIMARY TEETH WOULD HAVE BEEN NECESSARY AND APPROPRIATE TREATMENT. THIS PT IS ACTUALLY WORSE OFF NOW, THAN WHEN SHE STARTED. SHE NOW HAS TO SEEK RE-TREATMENT IN MY OFFICE AND UNDER MY DIRECT CARE. HAD (B)(6) DONE MORE THAN JUST MAIL HER SOME PLASTIC TRAYS, SHE COULD HAVE HAD A NICE RESULT AND NOT WASTED HER MONEY. THEY NEVER TOLD HER ABOUT HER IMPACTED PERMANENT TEETH, NOR OFFERED ANY OPTIONS THAT COULD HAVE BETTER SUITED HER ACTUAL NEEDS. A CASE LIKE THIS, TREATED BY A BOARD CERTIFIED ORTHODONTIST WOULD TAKE 24-30 MONTHS TO CORRECT USING BRACES ON THE TEETH, SO OFFERING SOMEONE A 6 MONTH TREATMENT WITH PLASTIC TRAYS TO CORRECT COMPLEX PROBLEM IS LIKE OFFERING ME A SCREWDRIVER TO HAMMER A NAIL INTO A WALL, IT'S THE WRONG TOOL FOR THE JOB. UNFORTUNATELY, (B)(6) IS ACTUALLY PRACTICING WITHOUT A LICENSE AND OFFERS NO SUPERVISION OF THE CASE. I DO NOT BELIEVE SHE WAS OFFERED ANY OPTIONS TO CONTINUE HER TREATMENT, ALTERNATIVE TO THEIR PRESCRIBED TREATMENT, OR RETAINERS TO HOLD HER TEETH IN POSITION. THEY STATE IN THEIR PRESS RELEASES THAT 750,000 PTS HAVE BEEN SUCCESSFUL TREATED, BUT OFFER NO MEASURE BY WHICH THESE CASES HAVE BEEN EVALUATED. IF THIS PT SHOWN HERE IS A SUCCESS, THEN IT IS NO WONDER THEY HAVE COME UP WITH THAT NUMBER. WHAT WE SADLY SEE MORE COMMONLY, IS PTS ARE BIKED OUT OF \$2000 AND MORE OFTEN THAN NOT LEFT WITH INCOMPLETE ORTHODONTIC CARE AND NO OPTIONS OR RECOURSE. PLEASE SEE THE ATTACHED PHOTOS AND X-RAYS THAT DEPICT THE FINAL "SUCCESSFUL" RESULT OF THIS PT'S TREATMENT. CLEARLY IT IS BELOW THE STANDARD OF CARE FOR ANY DENTAL PROFESSIONAL AND THUS THIS PT SHOULD BE ENTITLED TO A REFUND AT A MINIMUM AND LEGAL RECOURSE IDEALLY. FDA SAFETY REPORT ID# (B)(4).

**Concomitant Medical****Products (F):****INITIAL REPORTER INFORMATION (G)****Name (G1):****Company (G1):****Email (G1):****Address (G1):****Phone (G1):****Fax (G1):****Health Professional (G2):** Y**Also Reported To (G4):**

Manufacturer:  
User Facility: N  
Distributor/Importer:  
Y

**Occupation (G3):****NOT Releasable (G5):**



# **Exhibit 3**

**EXHIBIT FILED UNDER SEAL**

# Exhibit 4

## SUS VOLUNTARY EVENT REPORT (FOI for Manufacturers)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5093023	SMILE DIRECT CLUB / ALIGN TECHNOLOGY INC.	14-FEB-2020	18-FEB-2020 12:06:18.00

## Event Information

Event Date (B3):	17-JUL-2019	Event Report Type (H1):	Serious Injury	Adverse Event (B1):	Y
Report Date (B4):	12-FEB-2020	Event Outcome (B2):	Required Intervention		
		Reporter Occupation (G3):	PATIENT		
Problem (B1):	Y				

## Device Information - 1

Product Code (E2b): ALIGNER, SEQUENTIAL (NXC)

Brand (E1): SMILE DIRECT CLUB INVISIBLE ALIGNERS

Device Type (E2): ALIGNER, SEQUENTIAL

Model #(E4):

Catalog #(E4):

Lot # (E4):

Other # (E4):

Implant Date (E6):

Explant Date (E7):

Expiration Date (E4):

Single Use (E8):

Device Available for  
Evaluation (C): NDate Device Returned to Mfr  
(C):

## Mfr Contact Name and Address (E3)

E3 ? Mfr Name: SMILE DIRECT CLUB / ALIGN  
TECHNOLOGY INC.

Address (E3):

## SUS VOLUNTARY EVENT REPORT (FOI for Manufacturers)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Description**

(B5):

Date FDA received: 14-FEB-2020

Voluntary 18-FEB-2020 12:06:18.00:

I USED SMILE DIRECT CLUB ALIGNERS BACK IN 2016 TO CORRECT MY TEETH. I WAS TOLD IN (B)(6) 2019 BY MY GENERAL DENTIST THAT I HAD RECEDING GUMS AND MOVEMENT IN MY BOTTOM TWO FRONT TEETH THAT WAS CONSISTENT WITH BONE LOSS. I FOLLOWED UP WITH THE (B)(6) TO SEE WHAT COULD BE DONE TO PREVENT FURTHER DAMAGE. THEY CONFIRMED WITH X-RAYS AND BONE DENSITY SCAN THAT THE BONE PROTECTING MY FRONT BOTTOM TEETH WAS COMPLETELY GONE AS WELL AS THE BONE BETWEEN THE TEETH ALLOWING THEM TO WIGGLE. WITHOUT CORRECTING THIS OVER THE YEARS I WAS TOLD I COULD LOSE THESE TWO TEETH. THEY ARE INCREDIBLY PAINFUL AND SENSITIVE DUE TO THE EXPOSED ROOTS. I CAN ACTUALLY SEE THE WHITE ROOTS COMPLETELY EXPOSED WHEN I PULL DOWN MY FRONT BOTTOM LIP AND IS SO SEVERE THE GUMS ARE COMPLETELY GONE. I ALSO FOLLOWED UP PERIODONTICS AND WAS TOLD THAT I HAVE SEVERE GUM RECESSON ON ALMOST ALL MY FRONT TEETH THAT REQUIRE ALLOGRAFTS WHICH WILL BE PAINFUL AND EXPENSIVE BUT ARE NECESSARY TO HELP STABILIZE THE TEETH AND PROTECT THE ROOTS. THIS PERMANENT DAMAGE WAS DUE TO SMILE DIRECT CLUB NOT TAKING IN ACCOUNT THE BONE AROUND THE TEETH AND PUSHING THE TEETH TOO TOWARD WITH TOO MUCH FORCE AND THEN GAVE ME AN IMPROPER FITTING RETAINER WHICH PERPETUATED THE DAMAGE. THIS BONE LOSS I AM TOLD IS PERMANENT AND THE GUM ALLOGRAFTS WILL HELP WITH STABILIZATION, BUT I WILL LIKELY HAVE CONTINUED SENSITIVITY ISSUES. I NOW HAVE TO GO THROUGH ANOTHER ROUND ORTHODONTIC TREATMENT WITH INVISALIGN TO RECLINE AND PUT MY TEETH BACK INTO THE BONE AND FIX TRAUMATIC OCCLUSION CAUSED BY IMPROPER MOVEMENT OF MY TEETH THEN PROCEED WITH MULTIPLE SURGERIES FOR PLACEMENT OF THE GUM GRAFTS. SMILE DIRECT HAS COST ME SO MUCH PAIN AND MONEY AND THEY NEED TO BE SHUT DOWN. I'VE SAT IN MANY A DENTIST CHAIRS IN TEARS AFTER BEING TOLD ABOUT ALL THE DAMAGE THEY CAUSED MY MOUTH. I NEVER WANT THIS TO HAPPEN TO ANOTHER UNSUSPECTING PERSON LOOKING TO STRAIGHTEN THEIR TEETH FOR CHEAP. I ACTUALLY FOUND THAT INVISALIGN IN THE FIRST PLACE WOULD HAVE BEEN A CHEAPER OPTION AND THEIR CLAIMS THAT THEY ARE CHEAPER OPTION IS FALSE WHEN YOU TAKE IN ACCOUNT THE MONEY IT WILL TAKE TO FIX THE PROBLEMS THEY CAUSED ME. I HAD NO F/U WITH AN ORTHODONTIST DURING MY SMILE DIRECT CLUB TREATMENT, NEVER TALKED TO AN ORTHODONTIST AND TOOK MY OWN IMPRESSIONS. NOW HAVING INVISALIGN AND SEEING WHAT THE F/U SHOULD BE LIKE, I AM SHOCKED THAT I NEVER HAD A CONVERSATION WITH AN ORTHODONTIST TO DISCUSS MY TREATMENT WHICH I FEEL ULTIMATELY LED TO MY PERMANENT DAMAGE ALONG WITH THE FAULTED AI DESIGNED TREATMENT. I DID NOT F/U WITH THE COMPANY BECAUSE AFTER SOME RESEARCH THERE ARE MANY STORIES LIKE MINE. I HAD TERRIBLE EXPERIENCE WITH CUSTOMER SERVICE DURING MY TREATMENT AND FOUND IT IMPOSSIBLE TO GET HELP WITH ISSUES AND WAS PUT ON HOLD FOR 30 MINS AT A TIME WHEN ISSUES AROSE AND FELT THAT TRYING TO REPORT IT TO THEM WOULD BE A LONG FEAT. I WENT STRAIGHT TO FDA TO REPORT THAT THIS PRODUCT IS CAUSING PEOPLE REAL BODILY DAMAGE AND HARM. I WILL TRY TO CONTACT THEM TO SEND ME MY TREATMENT PLAN AND DIAGNOSTIC PICTURES TO BE USED AS REFERENCE FOR THE DAMAGE TO MY GUMS BEFORE AND AFTER TREATMENT. FDA SAFETY REPORT ID# (B)(4).

Concomitant Medical  
Products (F):

**INITIAL REPORTER INFORMATION (G)**

Name (G1):

Company (G1):

Email (G1):

Address (G1):

Phone (G1):

Fax (G1):

Health Professional  
(G2): \*

Also Reported To (G4):

Manufacturer:  
User Facility: N  
Distributor/Importer:

SUS VOLUNTARY EVENT REPORT (FOI for Manufacturers)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

Occupation (G3): PATIENT

NOT Releasable (G5): N

# Exhibit 5



Limited-time offer.



**60% less than Invisalign.<sup>1</sup> More premium perks.**



Choose value. Choose smile. Get started today for this exclusive offer:

- [Free 3D scan](#) or [\\$12 impression kit](#)
- Free Premium Whitening Kit (\$40 value)
- 1 free Club Edition Electric Toothbrush (\$23 value)
- Plus, be entered for a chance to win free aligners (\$2050 value)<sup>2</sup>

**Use code: BRIGHTBRUSH22**

**Free scan**

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OR

**\$12 kit**

[Order my kit](#)

*Hurry - offer ends 11/4/2022.*



## Free oral care products.

Get a Premium Teeth Whitening Kit and Club Edition Electric Toothbrush + Aligner Brush for free when you complete your scan or return your impressions.

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## The smarter choice.

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**Invisalign**

**Doctor-directed care**

Lifetime Smile Guarantee™ 3	—
Treatment plan time 4–6 months 4	Treatment plan lengths vary greatly
No markup	3x markup 5
Nighttime-only option	—
\$2050 6 or less than \$89/month	Average \$5200 7

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## **“The time has flown by.”**

Jasmine (12) found her aligners quickly became part of her schedule – but what really surprised her was how quickly they straightened her teeth.

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**Impression Kit Offer:** Within ten (10) business days after your completed impression kit is returned and your photos have been uploaded to your [customer portal](#) you will receive a digital claim code via email to collect a rebate for the amount you paid for the impression kit in the form of a digital Visa® Prepaid card. A claim code email will be sent to the email address associated with your impression kit. You will have four (4) months from receipt of the claim code to claim your rebate. [See full terms here.](#)

**Toothbrush Bundle Offer:** After you have completed your SmileShop appointment and 3D scan at a SmileDirectClub location or returned your completed impression kit and uploaded photos to your [customer portal](#), you will receive an email to collect your free club edition electric toothbrush and 6 months of whitening kit in the form of a digital SmileStore Prepaid card. An email with instructions to claim your prepaid card will be sent to the email address associated with the SmileShop appointment or impression kit order within 10 business days of your appointment or the receipt of your impression kit. Restrictions apply. This offer is only open to legal residents of the United States. To obtain your digital SmileStore Prepaid card, you must book your SmileShop appointment or order your impression kit with SmileDirectClub from 11/2/2022 through 11/12/2022 and enter the promo code BRIGHTBRUSH22 where directed.

**60% less than Invisalign:** "60% less than braces and Invisalign" based on Single Pay vs. avg. fees (incl. diagnostics and exams) for braces or Invisalign treatment, as reported in nat'l surveys of dentists and orthodontists. Comparison does not include added costs, such as retainers, and is limited to mild-to-moderate teeth correction,

as braces and Invisalign may treat additional issues.

<sup>2</sup>**Aligner Giveaway:** NO PURCHASE NECESSARY. Void where prohibited. The sweepstakes runs from 11/2/2022 through 12/31/2022. Open to legal residents of the United States. Three (3) methods of entry: (i) book and complete a scan, (ii) order and submit an impression kit, or (iii) mail in entry. Limit 1 entry per person. [See Official Rules here for complete entry/prize details.](#) SmileDirectClub, 414 Union St., Ste. 800, Nashville, TN 37219.

<sup>3</sup> SmileDirectClub treatment is backed by our [Lifetime Smile Guarantee™](#). Terms and conditions apply. See [See SmileDirectClub.com/guarantee for details.](#)

<sup>4</sup> Typical SmileDirectClub treatment takes 4–6 months. [See SmileDirectClub.com/claims for details.](#) Results may vary.

<sup>5</sup> "3x markup" claim based on the average cost of Invisalign aligners charged to the orthodontist by Align Technology, Inc., as compared to the average total fees (including diagnostics and in-person exams) charged to the consumer by the dentist or orthodontist for treatment of mild-to-moderate malocclusion with Invisalign, as reported in a 2021 national survey of practicing dentist and orthodontists. Results may vary.

<sup>6</sup> Cost of SmileDirectClub aligners based on Single Pay. SmilePay™ is \$89/month for 26 months with \$250 deposit (\$2564 total). APR varies. [See SmileDirectClub.com/pricing/apr-financing](#) for financing details for your state.

<sup>7</sup> Cost of Invisalign based on average total fees (including diagnostics and in-person exams) for treatment of mild-to-moderate malocclusion with Invisalign as reported in a 2021 national survey of practicing dentists and orthodontists. Results may vary.

# Exhibit 6



## SUS VOLUNTARY EVENT REPORT (FOI for Manufacturers)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5090617	SMILEDIRECTCLUB / ALIGN TECHNOLOGY, INC.	23-OCT-2019	24-OCT-2019 13:31:55.00

## Event Information

Event Date (B3):	15-FEB-2019	Event Report Type (H1):	Serious Injury	Adverse Event (B1):	Y
Report Date (B4):	22-OCT-2019	Event Outcome (B2):	Disability/Permanent Damage, Required Intervention		
		Reporter Occupation (G3):	PATIENT		
Problem (B1):	Y				

## Device Information - 1

Product Code (E2b): ALIGNER, SEQUENTIAL (NXC)  
 Brand (E1): INVISIBLE ALIGNERS  
 Device Type (E2): ALIGNER, SEQUENTIAL

Model #(E4):

Catalog #(E4):

Lot # (E4):

Other # (E4):

Implant Date (E6): 07-FEB-2019

Explant Date (E7): 07-MAY-2019

Expiration Date (E4):

Single Use (E8): \*

Device Available for  
Evaluation (C): Y

Date Device Returned to Mfr  
(C):

## Mfr Contact Name and Address (E3)

E3 ? Mfr Name: SMILEDIRECTCLUB / ALIGN  
TECHNOLOGY, INC.

Address (E3):

## SUS VOLUNTARY EVENT REPORT (FOI for Manufacturers)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Description****(B5):****Date FDA received:** 23-OCT-2019

Voluntary 24-OCT-2019 13:31:55.00:

THIS IS IN REGARDS TO MY TEETH ALIGNMENT ISSUE WITH (B)(6). I VISITED ONE OF THEIR BAY AREA BRANCHES IN (B)(4) ON (B)(6) 2019. I WANTED TO REDUCE FLARING PROTRUSION ON MY UPPER ANTERIOR TEETH WITH THEIR INVISIBLE ALIGNERS TO BE WORN FOR SIX MONTHS (180 DAYS) AS PER THEIR ADVERTISEMENT. THEIR STORE REP TOOK THE 3D PHOTOS OF MY TEETH AND SIGNED ME UP ON THE SAME DAY. I REQUESTED THAT I NEED THE SDC'S ORTHODONTIST ANALYSIS REPORT RX ON THOSE IMAGES BEFORE THEY CHARGE MY CREDIT CARD AND MAIL ME THE ALIGNERS. HOWEVER, ON THE FOLLOWING DAY ((B)(6) 2019) I GOT THEIR EMAIL STATING THAT I WAS SIGNED UP RIGHT AWAY, WITH INVISIBLE ALIGNERS BEING CREATED. THAT EMAIL MENTIONED ABOUT CUSTOM-MADE ALIGNERS AS PER TREATMENT PLAN BUT THEY HAD NOT PROVIDED ME ANY SUCH PLAN AND THEY CHARGED MY CREDIT CARD. THEY SENT ME THE INVISIBLE ALIGNERS WITHIN A WEEK ON (B)(6) 2019 AND STILL DIDN'T PROVIDE THE SDC'S ORTHODONTIST REPORT. I PRESUMED I COULD USE THOSE ALIGNERS AS THEIR SDC'S ORTHODONTIST MUST HAVE EVALUATED AND DESIGNED THEM BASED ON MY NEEDS. CLOSE TO THE END OF 90 DAYS, I WAS UNABLE TO WEAR THE ALIGNERS DUE TO SEVERE PAIN AND HAD TO BOOK AN APPT WITH SDC AT THE SAME REDWOOD CITY LOCATION. THE PAIN BEGAN FROM THE WEEK 2 ((B)(6) 2019) OF STARTING TO WEAR THE ALIGNERS AND PERSISTED ALL THROUGHOUT THE 90 DAY TREATMENT PERIOD. I HAD TO BEAR THE PAIN THINKING THAT IT WAS AN INNATE COMPONENT OF SDC'S TREATMENT PROCESS. WHEN I WENT BACK FOR 90 DAYS PROGRESS EVALUATION AFTER USING THEIR ALIGNERS, THEIR REP SAID THAT THE CORRECTION OF PROTRUSION IS NOT POSSIBLE AND THE ALIGNERS WERE JUST MEANT TO REDUCE THE GAP BETWEEN TEETH. SDC CUSTOMER SUPPORT ALSO EMAILED ME THE SAME. I HAD TO GO THROUGH SO MUCH OF PAIN DAY AND NIGHT FOR THOSE 90 DAYS USING SDC ALIGNERS WHICH I THOUGHT WOULD ORTHODONTICALLY REPOSITIONED AND ELIMINATE FLARING IN MY UPPER ANTERIORS AND THUS WOULD ACHIEVE A STRAIGHT EDGE TO EDGE BITE. I WAS NEVER TOLD BEFORE BEGINNING TREATMENT THAT THE PURPOSE I DESIRED COULD NOT BE ACHIEVED WITH SDC ALIGNERS AND SDC'S TREATMENT PLAN RX. I COULDN'T EVEN BITE AN APPLE ALL THOSE DAYS BECAUSE OF THE PAIN AND SENSITIVITY THOSE ALIGNERS CREATED ON TO MY TEETH. AFTER GOING THROUGH ALL THESE INCONVENIENCE OF WEARING PAIN PRODUCING ALIGNERS FOR 90 DAYS FOR NO ORTHODONTIC BENEFIT. DUE TO SDC'S FALSE PROMISE AND THE DELAY IN PROVIDING ME THE INFO THAT THE REDUCTION IN FLARED UPPER ANTERIORS TO CREATE A STRAIGHT EDGE TO EDGE BITE CANNOT BE ACHIEVED. I ASKED THEM TO CANCEL FURTHER PROCEDURES. I ALSO HAD DENTAL CROWNS ON SOME OF MY TEETH WHICH UNDERWENT ROOT CANAL TREATMENT BEFORE. BECAUSE OF THE FRICTION, PAIN AND REALIGNMENT OF MY TEETH WITH THE USE OF SDC INVISIBLE ALIGNERS, ONE OF MY DENTAL CAPS ALSO FELL OFF AND I HAD TO APPROACH A DENTIST TO FIX THAT TOOTH BUT MY GUMS WERE SWOLLEN AND BECAME SENSITIVE. WHEN I CONSULTED AN ORTHODONTIST LATER, HE SAID THE FALLING OFF OF MY EXISTING CROWN WAS PROBABLY DUE TO THOSE ALIGNERS. IN ADDITION, HE TOLD ME THAT THE SEVERE PAIN AND DISCOMFORT I WENT THROUGH FOR 3 MONTHS WITH SDC TREATMENT PLAN IS NOT SOMETHING WHICH WOULD HAPPEN WITH A METHODOLOGICAL CORRECTION WHEN AN ORTHODONTIST IS INVOLVED WHO WOULD TAKE CLOSE OBSERVATION THROUGHOUT THE TREATMENT PERIOD. NO DENTIST MONITORED ME DURING THE THREE MONTHS I SUFFERED WITH SDC'S TREATMENT ALIGNERS WHICH I NOW HAVE LEARNED WERE DOOMED TO FAIL AND THEY DID FAIL. SDC'S MAIL ORDER ALIGNERS PROVIDED THE WRONG TREATMENT PLAN AND TREATMENT. THE CORRECT TREATMENT REQUIRED AN ORTHODONTIST'S TRAINING, KNOWLEDGE AND HANDS ON TREATMENT. SDC'S MAIL ORDER ALIGNERS DID NOT AND COULD NOT EVER PROVIDE CORRECT ORTHODONTIC TREATMENT BECAUSE NO SDC DENTIST EVER EXAMINED OR TREATED ME IN PERSON TO DESIGN THE CORRECT ORTHODONTIC TREATMENT AND MONITOR ITS PROGRESS. SDC'S TREATMENT WAS USELESS, A WASTE OF MY TIME, PAINFUL AND NO BARGAIN. FDA SAFETY REPORT ID# (B)(4).

**Concomitant Medical** NONE**Products (F):****INITIAL REPORTER INFORMATION (G)****Name (G1):****Company (G1):****Email (G1):****Address (G1):****Phone (G1):****Fax (G1):**

## SUS VOLUNTARY EVENT REPORT (FOI for Manufacturers)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

<b>Health Professional (G2):</b>	*	<b>Also Reported To (G4):</b>	UNITED STATES Manufacturer: User Facility: N Distributor/Importer:
<b>Occupation (G3):</b>	PATIENT	<b>NOT Releasable (G5):</b>	N

# Exhibit 7

## SUS VOLUNTARY EVENT REPORT (FOI for Manufacturers)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5090459	SMILEDIRECTCLUB / ALIGN TECHNOLOGY, INC.	17-OCT-2019	18-OCT-2019 10:44:43.00

## Event Information

Event Date (B3):	02-FEB-2018	Event Report Type (H1):	Serious Injury	Adverse Event (B1):	Y
Report Date (B4):	16-OCT-2019	Event Outcome (B2):	Required Intervention		
		Reporter Occupation (G3):	PATIENT		
Problem (B1):	Y				

## Device Information - 1

Product Code (E2b): ALIGNER, SEQUENTIAL (NXC)  
 Brand (E1): ORTHODONTIA  
 Device Type (E2): ALIGNER, SEQUENTIAL

Model # (E4):

Catalog # (E4):

Lot # (E4):

Other # (E4):

Implant Date (E6):

Explant Date (E7):

Expiration Date (E4):

Single Use (E8):

Device Available for  
Evaluation (C): Y

Date Device Returned to Mfr  
(C):

## Mfr Contact Name and Address (E3)

E3 ? Mfr Name: SMILEDIRECTCLUB / ALIGN  
TECHNOLOGY, INC.

Address (E3):

## SUS VOLUNTARY EVENT REPORT (FOI for Manufacturers)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Description****(B5):****Date FDA received:** 17-OCT-2019

Voluntary 18-OCT-2019 10:44:43.00:

I OBTAINED ALIGNERS THROUGH SMILE DIRECT CLUB IN (B)(6) 2018, AFTER BEING FURNISHED AN IDEAL, CORRECTED SMILE DEPICTION IN RETURN FOR MY HOME DENTAL IMPRESSIONS AND PHOTOGRAPHS. I WAS ASSURED IN WRITING MY TREATMENT WOULD BE OVERSEEN BY AN ORTHODONTIST IN MY STATE OF RESIDENCE, (B)(6). FROM THE BEGINNING OF TREATMENT (WHICH I WAS TOLD WOULD CONCLUDE IN 8 MONTHS), I EXPERIENCED A NUMBER OF PROBLEMS, AND CONTACTED SMILE DIRECT CLUB ABOUT THEM. CHIEF AMONG MY COMPLAINTS WAS DIFFICULTY CHEWING FOOD. I WAS TOLD THIS WAS A NORMAL REACTION TO THE REALIGNMENT OF MY TEETH AND NOT CAUSE FOR CONCERN. I TRACKED DOWN THE ORTHODONTIST ASSIGNED TO MY CASE; HE WAS DR (B)(6). I ATTEMPTED TO SCHEDULE A TRIP TO HIS OFFICE (FOUR HOURS FROM MY HOME) FOR AN IN-PERSON CONSULTATION ABOUT THE PROBLEMS I WAS HAVING, BUT WAS INFORMED THIS WAS IMPOSSIBLE. I CONTACTED SMILE DIRECT REPEATEDLY, BY PHONE AND EMAIL. THEIR RESPONSE WAS ALWAYS THE SAME: UNLESS I WAS EXPERIENCING A GREAT DEAL OF PAIN, MY DIFFICULTIES WERE NORMAL DURING ORTHODONTIC TREATMENT. WHEN MY FULL SET OF ALIGNERS HAD BEEN WORN AS PRESCRIBED AND MY "SMILE" WAS TO HAVE BEEN CORRECTED ((B)(6) 2018), MY TEETH WERE STILL NOT STRAIGHTENED AND I HAD MORE TROUBLE THAN EVER CHEWING AND DIGESTING FOOD. AT THIS POINT, SMILE DIRECT'S RESPONSE TO MY CONCERNS WAS TO SCHEDULE AN APPT FOR ME AT THEIR (B)(6) "SMILE SHOP" FOR RE-EVALUATION ON (B)(6) 2018. I MADE THAT TRIP AND THEIR TECHS DID SOME SORT OF IMAGING. I COMPLAINED THAT I WAS UNHAPPY WITH THE PROGRESS OF MY CASE UNDER DR (B)(6) SUPERVISION, AND REQUESTED A NEW ORTHODONTIST. I HAD DISCOVERED, BY THIS TIME, DR (B)(6) WAS BORN IN (B)(6) AND (B)(6) OF AGE IN 2018. AFTER TRYING REPEATEDLY TO CONTACT HIS (B)(6) "OFFICE", I BEGAN TO WONDER IF HE MAINTAINED AN ACTIVE PRACTICE OF ANY SORT. I ALSO ATTEMPTED TO LOCATE AN OFFICE IN (B)(6) FOR DR (B)(6), AND FOUND ONLY THAT HE WAS SOMEHOW LICENSED IN THE STATE IN 2016. HE HAS NO (B)(6) OFFICE, DESPITE SMILE DIRECT'S CLAIM. ABOUT A MONTH AFTER THAT TRIP, I RECEIVED A NEW SET OF ALIGNERS ISSUED BY "DR (B)(6)" (ADDRESS UNK). I BELIEVE THEY WERE ABOUT EIGHT WEEKS' WORTH. ONE GLANCE AT THE ALIGNERS SHOWED THE FINAL SET DID NOT PUT FULLY STRAIGHTENED TEETH - I WORE THEM RELIGIOUSLY, ANYWAY. THEN I REQUESTED NEW ALIGNERS. I WAS SENT AN IMPRESSION KIT, ASKED FOR PHOTOGRAPHS, ISSUED A NEW SET. THROUGHOUT THIS TIME, I COMPLAINED REPEATEDLY ABOUT MY BITE AND WAS TOLD IT WAS NORMAL TO EXPERIENCE DIFFICULTIES UNTIL TREATMENT WAS COMPLETED. I ASKED FOR AND RECEIVED ALIGNERS AGAIN, AND WAS ADAMANT I DIDN'T WANT THEM TO SEND ME A SET THAT RESULTED IN ANYTHING LESS THAN STRAIGHTENED TEETH, REGARDLESS OF THE NUMBER OF SETS THEY ISSUED. SMILE DIRECT'S RESPONSE WAS TO SEND ANOTHER SIX WEEKS OF ALIGNERS, ALONG WITH A REFUND OF (B)(6) AND THE PROMISE OF FREE RETAINERS WHEN MY TEETH WERE FULLY STRAIGHTENED. AT EACH OF THESE JUNCTURES, I HAD TO KEEP WEARING OUTDATED ALIGNERS AND WAIT THROUGH THE LENGTHY PROCESS OF SMILE DIRECT ISSUING AND SHIPPING AN IMPRESSION KIT, USING AND RETURNING IT IMMEDIATELY, THEN GETTING THROUGH AN EXTREMELY EXTENDED PERIOD THEY TOOK TO CREATE AND MAIL NEW ALIGNERS. DESPITE MY INSISTENCE, NONE OF THESE SETS OF ALIGNERS RESULTED IN STRAIGHT TEETH. THEY WERE BETTER, MIND YOU, BUT FAR FROM STRAIGHT (AND COMPLETELY DIFFERENT FROM THE ANIMATED "TRANSFORMATION" OF MY SMILE I'D BEEN ASSURED WOULD OCCUR). I GAVE UP I SETTLED, BECAUSE I KNEW SMILE DIRECT WOULD CONTINUE SENDING ME ALIGNERS IN AN ENDLESS CYCLE FOR YEARS, BUT MY TEETH WOULD NEVER COME CLOSE TO THE RESULT THEY'D PROMISED. MY BITE WAS STILL SO MESSED UP I COULDN'T CHEW PROPERLY, THOUGH, I AM NOW BEING TREATED BY A LICENSED ORTHODONTIST NEAR MY HOME FOR THE PROBLEMS CAUSED BY SDC. IT BOGGLES MY MIND THAT I HAVE TO TAKE MY DOG TO SEE A VETERINARIAN AND OBTAIN A PRESCRIPTION FOR FLEA MEDS TO BE ORDERED ONLINE, BUT SDC IS REMODELING BONE WITH NO PT EXAMS. FDA SAFETY REPORT (B)(4).

**Concomitant Medical****Products (F):****INITIAL REPORTER INFORMATION (G)****Name (G1):****Company (G1):****Email (G1):****Address (G1):****Phone (G1):****Fax (G1):**

## SUS VOLUNTARY EVENT REPORT (FOI for Manufacturers)

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UNITED STATES

Health Professional  
(G2): \*

Also Reported To (G4):

Manufacturer:  
User Facility: N  
Distributor/Importer:

Occupation (G3): PATIENT

NOT Releasable (G5):

N

# Exhibit 8



April 25, 2019

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061, HRA-305  
Rockville, MD 20852

Re: Citizen Petition—Misbranding by SmileDirectClub, LLC, of Its  
Orthodontic Plastic Bracket Device and Dental Impression Material Products

To Whom It May Concern:

The basis for this petition is straightforward: SmileDirectClub, LLC, (SDC) is placing the public at risk by knowingly evading the “by prescription only” restriction that the FDA has placed on plastic teeth aligners<sup>1</sup> and on dental impression material.<sup>2</sup> For all intents and purposes, SDC sells its plastic teeth aligner and dental impression material products to consumers over-the-counter.

Clearly, SDC is not patient focused. In lieu of having dentists perform patient exams meeting the applicable standard of care as the basis for prescribing orthodontic treatment, SDC tries to protect its own commercial interests by requiring customers to self-certify their dental condition and then hold SDC harmless from any negative consequences suffered as a result of SDC's aligner “treatment therapy.”

#### **A. ACTION REQUESTED**

By skirting the “by prescription” restriction with regard to its devices, SDC is misbranding its products and violating labeling laws. Therefore, Petitioner, American Dental Association, requests the FDA to:

- Move for an injunction against SDC's further sale and distribution of its misbranded teeth aligner and dental impression material products in interstate commerce;

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<sup>1</sup> The FDA Classification Name for these aligner devices is Orthodontic Plastic Brackets (Sequential Aligners), 21 C.F.R. § 872.5470. They are referred to as teeth aligners or plastic teeth aligners herein.

<sup>2</sup> The FDA Classification Name for materials for taking dental impressions, which SDC refers to as “putty”, is Impression Material, 21 C.F.R. § 872.3660.

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- Seek a condemnation and seizure order directed to SDC's misbranded teeth aligner and dental impression material products being distributed and sold in interstate commerce;
- Levy a significant civil penalty against SDC in connection with its misbranded teeth aligner and dental impression material products being distributed and sold in interstate commerce;<sup>3</sup> and,
- Request SDC to voluntarily undertake a Class II recall of its misbranded teeth aligner and dental impression material products being distributed and sold in interstate commerce.

It is prohibited to introduce or cause to be introduced into interstate commerce any device that is misbranded. Federal Food Drug & Cosmetic Act (FD&C Act) § 301(a) [21 U.S.C. § 331(a)].

Further, it is prohibited to misbrand or cause the misbranding of a device in interstate commerce. FD&C Act § 301(b) [21 U.S.C. § 331(b)].<sup>4</sup>

The law provides, in part, that, "[t]he district courts of the United States [. . .] shall have jurisdiction, for cause shown to restrain violations of § 331." FD&C Act § 302 [21 U.S.C. § 332]. Petitioner requests the FDA to seek, pursuant to FD&C Act § 302(a) [21 U.S.C. § 332(a)], an injunction against SDC from manufacturing or continuing to manufacture and from continuing to distribute and sell in interstate commerce SDC's plastic teeth aligner and dental impression material products. Absent such an injunction there is a likelihood that SDC's misbranding violations will continue.

As provided in FD&C Act § 304(a)(1) & (2) [21 U.S.C. § 334(a)(1) & (2)], any misbranded device, "shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which they are found." Petitioner requests that the FDA bring a condemnation and seizure proceeding directed to SDC's teeth aligner and dental impression material products that are shipped and sold in interstate commerce.

Pursuant to FD&C Act § 303(f)(1)(A) [21 U.S.C. § 333(f)(1)(A)], "any person who violates a requirement of [Chapter 9 – Federal Food, Drug, and Cosmetic Act] which relates to devices

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<sup>3</sup> In addition to civil penalties, the FDA can impose criminal penalties under FD&C Act § 303(a)(1) and/or (a)(2) [21 U.S.C. § 333(a)(1) and/or (a)(2)].

<sup>4</sup> Petitioner alleges that SDC violated the following misbranding provisions: FD&C Act §§ 502(a)(1), (f)(1), (o), (q)(1), (q)(2), [21 U.S.C. §§ 352(a)(1), (f)(1), (o), (q)(1), (q)(2)].

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shall be liable to the United States for a civil penalty.” Petitioner requests that the Secretary of Health and Human Services assess a civil penalty in accordance with the factors relevant to determining the amount of a civil penalty in FD&C Act § 303(f)(5)(B) [21 U.S.C. § 333(f)(5)(B)].

Petitioner respectfully requests that the FDA proceed in accordance with 21 C.F.R. § 7.45 and exhort SDC to undertake a voluntary Class II recall of its plastic teeth aligner and dental impression material products that are shipped and sold in interstate commerce.

Further, Petitioner urges the FDA to undertake whatever additional corrective action it deems appropriate in the light of the facts and circumstances detailed herein.

## **B. STATEMENT OF GROUNDS**

### **Summary**

We live during a time of “disruptive technologies” made possible by advances in material science, biology, digitalization, and even newly conceived business models. Where such developments increase efficiencies, lower costs, and expand access to consumers without increasing significant risks to the public such innovations can provide substantial boons.

But just as assuredly, when increased company profits or purportedly lower costs to consumers result from circumventing established, well-considered public health and safety practices, then the true costs, both in terms of injuries to and ultimate expense for those supposed to benefit, can turn out to be far higher than they are worth. In such situations the word “disruptive” loses its salutary glow. SDC’s business practices fall into this latter unfortunate category.

Despite describing itself in FDA filings as a mere “re-packager/re-labeler”, or “contract manufacturer”, and in court papers as “a dental support organization that provides administrative non-clinical support to dentists and orthodontists...”<sup>5</sup>, SDC is involved at every level in the manufacture, product sale, and service business of straightening teeth using plastic aligners, which are Class II devices regulated by the FDA. Plastic Aligners and Impression

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<sup>5</sup> *Scott D. Galkin, D.M.D. and New Jersey Dental Association v. SmileDirectClub, LLC, Danny Leeds, D.D.S., Robert M. DeRosso, D.M.D. and Isaac V. Perle, D.M.D.*, MID-C-19-19, Brief in Support of Defendant’s Motion to Dismiss, p. 3.



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Materials are subject to a “by prescription only” FDA restriction, which SDC effectively eludes. To any extent SDC may have lowered costs it has done so by recklessly selling “do-it-yourself dentistry” over-the-counter to its customers (these consumers are most definitely *customers* and not *patients*).

SDC has virtually eliminated from the process any substantive participation by a dentist in a customer’s teeth straightening treatment even with respect to the all-important comprehensive oral examination that should precede prescribing treatment in every instance. Instead, SDC “affiliated dentists” allegedly “assigned to your smile” sign-off on aligner orders solely on the basis of plastic impressions and mouth photos made by SDC customers or 3D scans and photos taken at SDC SmileShops. This approach may be commercially rewarding, but it utterly fails to meet the standard of care for a comprehensive oral examination and does not provide a basis upon which a valid prescription for orthodontic care can be written. [See, generally, Exhibit 5, Affidavit of Dr. Randall Markarian]

### **1. Regulatory History**

To fully understand SDC’s serious misbranding violations, it is helpful to briefly review the history of the FDA’s regulation of plastic teeth aligners and dental impression materials. From the beginning, these devices have been subject to the “by prescription only” restriction because they cannot be used safely “except under the supervision of a practitioner licensed by law to direct the use of such device.” As such, they are exempt pursuant to 21 C.F.R. § 801.109 from the “adequate directions for use” requirement of FD&C Act § 502(f)(1) [21 U.S.C. § 352(f)(1)]. This is because for such devices, “adequate directions for use” cannot be prepared for lay consumers. See, 21 C.F.R. § 801.109. SDC does not sell its products to consumers on the basis of valid prescriptions and wholly ignores the fact that “adequate directions for use” for its devices “cannot be prepared” for its consumers.

#### **a. FDA regulation of predicates to SDC’s plastic teeth aligner devices**

In 1998, Align Technology, Inc., (Align) filed a 510(k) request for clearance (number K981095) to market its plastic teeth aligner product sold under the Invisalign® System brand name. [Exhibit 1, PMN K981095] Align sought clearance for use of its product in the treatment of *mild to moderate* malocclusion. In granting clearance, the FDA designated Align’s product a

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Restricted Device requiring the label to bear, among other information, that its sale and distribution must be by prescription only in accordance with 21 C.F.R. § 801.109.

In 2008, Align filed its “Modified Invisalign® System 510(k) Premarket Notification” (number K081960). Selected pages from the 2008 filing are attached here as Exhibit 2. Align sought clearance for three labeling changes.<sup>6</sup>

Align explained that its system, “is a **doctor-prescribed** [emphasis added] series of removable plastic orthodontic aligners intended as an alternative to conventional wire and bracket technology.” [Exhibit 2, p.6]

The 2008 clearance included the contraindication of “active periodontal disease.” [Exhibit 2, p. 4] The 2008 submission also includes the “by prescription only” restriction and contains the following labeling language: “**Caution: Federal law restricts this device to sale by or on the order of a dental professional.**” [Exhibit 2, p.15]

In keeping with its Section 510(k) clearance, Align has sold its Invisalign® System through orthodontists and general dentists. The company continues to require dentists who prescribe the Invisalign® System to be trained in the use of the device. Align’s *Instructions for Use* are also consistent with the “by prescription only” restriction. [Exhibit 2, pp. 8-14] They are appropriately directed to the treating dentist, and include: A list of conditions to look for or to be aware of in a patient when considering or using the product, a description of various steps the dentist should take during the course of treatment, contraindications, allergy warnings, and reference to the Invisalign dentist training manual. As would be expected, many of these instructions would have very little meaning for lay consumers, and some would be incomprehensible to most.

#### **b. SDC’s Plastic Aligner Related FDA Filings**

In or around 2014, SDC first registered as a re-packager/re-labeler of Align’s Invisalign System plastic aligners under FD&C Act § 510 [21 U.S.C. § 360].<sup>7</sup> [Exhibit 3, Re-packager/Re-labeler

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<sup>6</sup> Align represented that, “[t]he technological characteristics of the modified and currently-marketed predicate device, such as design, raw material, and chemical composition, and their manufacturing process and related software, are identical. [Exhibit 2, p. 7]

<sup>7</sup> It did so under the name Access Dental Lab, LLC.

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Registration] It cited Align's 1998 510(k), (No. K981095). As a re-packager/re-labeler SDC should not have modified the indications for use or the restriction that such devices are "by prescription only."

But SDC did so by selling the aligners without a valid prescription, thereby rendering their product an over-the-counter item.

In March 2019, SDC registered itself as a contract manufacturer of aligners. [Exhibit 4, Contract Manufacturer Registration, 3/19] But it appears that SDC is actually a manufacturer of plastic aligners. Whereas a contract manufacturer is defined as an establishment that "[m]anufactures a finished device to another establishment's specifications", and so must merely register with the FDA"<sup>8</sup>, SDC manufactures its SmileLab finished aligners in accordance with its own specifications, including information derived from its customers' impression molds or the 3D scans taken of SDC customers at SDC's SmileShops.<sup>9</sup>

As a manufacturer of clear aligners for its own customers, SDC was legally obligated to seek 510(k) clearance, and it would have undoubtedly been subject to the same "by prescription only" restriction as the predicate devices. If SDC then decided to flout the restriction, as it has, it would have put its clearance in serious jeopardy. On the other hand, if SDC believed in good faith that the prescription restriction was somehow unnecessary, it could have explained in its clearance request why that was so.

As either a re-packager/re-labeler or a manufacturer changing the device from "prescription only" to OTC, which is what SDC has done, SDC was required to submit a pre-market notification informing the FDA of the prescription to OTC switch. This switch changed the environment of use of the aligners from use in a professional healthcare setting to that of home use. The FDA's guidance document, *Deciding When to Submit a 510(k) for A Change to an Existing Device*, states at p. 20 that, "changes from professional use to home use [...] are more likely to affect the device's risk profile and require submission of a new 510(k) because the

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<sup>8</sup> See,

<https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/registrationandlisting/ucm053165.htm>

<sup>9</sup> See, Exhibit 15, Q&A #5, "[s]ome aligners are produced by Invisalign and some by SDC's Smile Lab..."



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different environments have different levels of professional healthcare supervision and offer different environmental challenges.”

Moreover, SDC was legally bound to submit in its 510(k) proposed consumer oriented adequate directions for use in accordance with 21 C.F.R. § 801.5, since its device would no longer fall under the exemption of 21 C.F.R. § 801.109. As the FDA explains: “Directions for use necessary for health care professionals to use a device safely and effectively can be significantly different from the directions for use necessary for lay users to use that same device safely and effectively.” *Id.* at 17.

SDC failed to submit a premarket notification with proposed adequate directions for use in connection with its “by prescription” to OTC switch. SDC’s aligners are therefore misbranded in violation of FD&C Act §§ 502(f)(1) and (o) [21 U.S.C. §§ 352(f)(1) & (o)]. And, because SDC has circumvented the “by prescription” restriction set forth in 21 U.S.C. § 360(j)(e), instead selling the device OTC, the company is also violating FD&C Act § 502(q)(2) [21 U.S.C. § 352(q)(2)]

### **c. FDA regulation of dental impression material**

Impression material is used to provide models for study and for production of restorative prosthetic devices and the like. Although dental Impression Material is designated a Class II Device under 21 C.F.R. § 872.3660(b), Petitioner has found no evidence that SDC ever communicated at any level with the FDA about the Impression Material it sells to customers through the mail so they can make their own dental impressions that form the basis for the fabrication of their SDC aligners.<sup>10</sup> Such products are definitely subject to 510(k) review and from what Petitioner can determine all of them that have been submitted are covered by the “prescription use” restriction.<sup>11</sup> Presumably, this is due at least in part to the allergy, gagging, and choking risks they pose. [See, *infra*.]

SDC did not register itself as a distributor, manufacturer, or re-packager/re-labeler of the Impression Material, nor did it submit a new 510(k) clearance upon switching the impression

<sup>10</sup> This is one of two routes available to consumers purchasing SDC aligners, the other is to visit a SDC SmileShop for 3D scans. See, *infra*.

<sup>11</sup> See, e.g., 510(k) Numbers: K082560; K013129; K973781; K972239.

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device from prescription use to OTC use. SDC's failures in these regards rendered the device misbranded in violation of FD&C Act § 502(o) [21 U.S.C. § 352(o)] for failure to duly register under § 510 [21 U.S.C. § 360], failure to be included in a list required by § 510(j) [21 U.S.C. § 360(j)], and failure to provide notice and other information as required by § 510(k) [21 U.S.C. § 360(k)].

## 2. Orthodontic Exam Requirements for a Valid Prescription

Teeth are complex living organs comprising many elements. They have nerves and require blood circulation. Moving teeth that are next to other teeth, are rooted in bone, and are held in place by ligaments is often a complicated procedure dependent on multiple individual variables. There really isn't a "one-size-fits-all" methodology for providing competent, professional orthodontic treatment. Done improperly and without sufficient information the patient may not receive any benefit at all from treatment. Even worse, patients may be severely injured, suffering tooth loss, bone damage, nerve damage, jaw pain, exposed teeth roots, receded gums, aggravated or entirely new bite maladjustments, and other related injuries. [Exhibit 5, ¶ 17]

Without a comprehensive oral examination customers are at significantly higher risk for injuries attributable to their orthodontic treatment. This is why dentists are ethically and professionally obligated to know firsthand, before they prescribe treatment, the state of their patients' oral health. The information needed and the planning required cannot be reliably obtained merely from *customer* made dental impressions, photos, or 3D scans, and it certainly cannot be based primarily on patient self-reporting, which how SDC does things.

It is appalling that a dentist SDC spokesperson minimizes the very real health issues, and denigrates those who raise them with comments like, "[l]ook, this isn't rocket science or brain surgery, this is just moving teeth. Teeth move on their own all the time..."<sup>12</sup> The FDA clearly sees things differently from the SDC spokesperson, recognizing that "just moving teeth" requires expert knowledge and experience. That is why the FDA has designated plastic aligners and impression materials as "by prescription only" devices.

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<sup>12</sup> See, page 18, *infra*. This spokesperson goes on to say that dentists who raise these potential problems are "fearmongering", page 19, *infra*.



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If a patient has had a dental checkup in the recent past, the dentist evaluating the patient for orthodontic treatment can obtain a great deal of necessary information from reviewing the patient's dental record. It will show the last time the patient had a teeth cleaning, state whether the patient has active caries, which aligner therapy can aggravate, identify any crowns, bridges, implants, or other restorations and the state of those restorations (e.g., loose, broken, or missing fillings), which aligners can break, indicate whether an oral cancer screening was performed and its results, list any medications the patient is taking, detail any restricted airway issues caused by the patient's tonsils or otherwise, which can present problems for orthodontic treatment, note the presence of chronic dry-mouth conditions, which can combine with orthodontic treatment in promoting tooth decay, and note whether the patient exhibits periodontal disease. [Exhibit 5, ¶¶ 8, 9]

A dentist evaluating a patient for orthodontic treatment will confirm what is in the patient's dental record by conducting his or her own examination of the patient. Of course, the treating dentist is responsible for filling in any relevant gaps in the record. This is a fundamental step in meeting the standard of care prior to prescribing treatment. For example, because the presence of periodontal disease is such a strong contraindication for aligner or other orthodontic treatment, the dentist should conduct a periodontal exam, including probing the patient's gums to discover any bleeding or tissue swelling, loss of attachment or bone loss, and to check for any loose teeth. The examining dentist will also take into account the shape and dimensions of the patient's palate. [Exhibit 5, ¶¶ 10, 22]

Reviewing radiographs is essential and not optional as well. With regard to periodontal health and related issues, orthodontic treatment should never be commenced until the health of the patient's maxillary and mandibular bones are assessed. Any bone deterioration, whether caused by trauma or infection, will profoundly affect the nature of the patient's treatment, unless treatment is ruled out entirely. Radiographs are central to this inquiry, unless the severe state of periodontal disease and bone loss is so evident from close visual observation and probing that treatment can be ruled out on that basis alone. [Exhibit 5, ¶¶ 11-14]

Correcting the results of poor treatment, to the extent it can be corrected, can be very expensive, time consuming, and sometimes painful. These conditions can be very difficult, painful, and expensive to correct, to the extent correction is even possible [Exhibit 5, ¶¶ 17] as

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some SDC patients have learned to their chagrin. [Exhibit 6, Better Business Bureau complaint, 8/6/18, "excruciating pain, possible nerve damage"; Exhibit 7, Better Business Bureau complaint, 10/30/18, teeth fanned out, roots showing through gums; Exhibit 8, Better Business Bureau complaint, 8/20/18, after treatment mouth doesn't close all the way, back teeth don't touch, jaw pain from bite problem; Exhibit 9, Better Business complaint, 11/9/18, cannot fully close bite, have problems with chewing]

It is impossible for Petitioner to know with certainty how many similar injuries to patients have occurred. One of the reasons for this is that a condition for settling a complaint against SDC is that the customer agrees not to discuss the issue with third parties, and the other is that Petitioner has not taken formal discovery of SDC. And, of course, some customers may not bother to report problems because of the disclaimer language contained in the SDC contract documents (see, *infra*.)

The risk of severe patient discomfort and injury are greatly decreased, or can be swiftly corrected, if a) the patient undergoes a complete orthodontic exam prior to being prescribed orthodontic treatment or, b) the patient receives follow-up care from the prescribing dentist. [Exhibit 5, ¶ 18] The whole reason for developing a doctor/patient relationship and providing professional care to a patient is the recognition that every patient is an individual and so prescription of treatment is based on that patient's unique set of oral health issues. [Exhibit 5, ¶ 17] The cold business calculation that a percentage of bad outcomes is just a cost (for the customer affected) of doing business is inimical to professional healthcare.

Moreover, it is not just the relatively rare conditions that SDC and its affiliated dentists overlook. Without really knowing whether a customer has unerupted wisdom teeth or supernumerary teeth, or periodontal disease, or shortened or reabsorbed roots, or loose fillings, crowns, and bridges, or temporomandibular joint dysfunction (TMJ),<sup>13</sup> SDC and its affiliated dentists are just taking a shot-in-the-dark when they sell aligners to customers. It is the customers, not they, who pay the price.

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<sup>13</sup> This painful jaw condition can be aggravated by orthodontic treatment or may even be caused by poorly fitting devices.



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### 3. SDC's Marketing and Customer Service Business

SDC's regulatory shortcuts and failure to ensure that its products are only sold subject to a valid prescription have certainly not hindered SDC's sales efforts across the country. SDC has created a huge market presence for itself. The company advertises extensively in broadcast and print media and is prominent on social media. Although it based its re-packager registration on Align Technology's superseded 1998 PMN, which was limited to using plastic aligners to correct mild to moderate malocclusion, and has represented in court proceedings that its product is limited to such applications<sup>14</sup>, its advertising does not appear to conspicuously explain that limitation and its marketing photos strongly imply otherwise.

In fact, any number of photos (including "before and after photos") SDC displays on its website, product packaging, and social media either show examples of severe malocclusion, or misleadingly suggest that its product can be used to treat severe malocclusion. [Exhibit 10, SDC photos] One photo shows a customer with active periodontal disease [Exhibit 11] which is the listed contraindication for Align's predicate device.

On SDC's website, customers are asked to fill out a short questionnaire. The questionnaire asks for seven pieces of information, three of which pertain to a customer's teeth. The consumer is asked to compare his or her teeth to three photos showing mild to extreme teeth crowding and to three others showing mild to extreme gaps between teeth. An individual self-reporting that he has both extreme crowding and extreme gaps received the almost immediate reply from SDC that "You're a great candidate." [Affidavit of Nicholas Lewis Ramirez, Exhibit 12, ¶¶ 8, 10; Aff. Ex. A]

A follow up email from SDC urges the potential customer to either visit a SDC SmileShop for 3D scans, or to register with SDC to receive dental impression material from which to make his own dental impression. The email states, "**[SDC] has helped thousands of people who had bite issues like yours.**" [Emphasis added] [Exhibit 12, ¶ 11; Aff. Ex. B]. Yet the Informed Consent section of SDC's "Consent and History" form, which the customer must sign before receiving aligners, requires acknowledgement that, "I further understand that my invisible aligner therapy

<sup>14</sup> *Scott D. Galkin, D.M.D., et al. v. SmileDirectClub, LLC, et al.*, MID-C-19-19, Brief in Support of Defendant's Motion to Dismiss, p. 3.

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treatment will address only the alignment of my teeth **and will not correct my existing bite condition.**" [Emphasis added] [Exhibit 13, SDC "History and Informed Consent Form, p. 4] Neither in the first follow-up email or in a subsequent marketing email from SDC's Chief Dental Officer is the potential customer told that a dentist will *prescribe* the customer's aligner treatment. Instead, SDC uses words like "guide your smile", and "approve your treatment plan." [Exhibit 12, Aff. Ex's B and C]

The most egregious example of SDC's false and misleading advertising is the representation made through SDC's Chief Dental Officer, Dr. Jeffrey Sulitzer, that:

An individual who is requesting treatment by using SmileDirectClub' aligners is receiving the same level of care from a treating dentist or orthodontist as an individual visiting a traditional orthodontist or dentist for treatment.

Dr. Sulitzer continues:

We define quality as the intersection of customer satisfaction and the Standards of Care. ... We utilize the Standard of Care established by the dental professional community.

[Exhibit 14, *The Grin Life*, SDC Blog, 4/3/2018, p. 10]

Of course, this is not true because there is no patient exam and so no valid prescription for treatment, and no follow up care, which are requirements of the minimum standard of care. With respect to the issue of follow up care, SDC even leaves it to customers to cut and reshape their aligners if they don't fit. [Exhibit 15, Facebook Q & A with Dr. Ben Burris, member SDC Clinical Advisory Board, 5/13/17, Q&A #19] Some SDC customers have bristled at this. [Exhibit 16, Better Business Bureau complaint, 7/10/2018]

SDC has made seriously false and misleading statements to its customers, some of whom have provided their specific examples. One concerns the issue of "bite correction." The customer told SDC that his goal was to have his underbite corrected, and was told that he was good candidate for SDC aligner treatment. But when the treatment failed and he protested, SDC directed him to the fine print of the Consent and History form stating that its aligners cannot correct bite problems. [Exhibit 17, Better Business Bureau complaint, 8/9/17; see, also, p.11, *supra*.].

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These examples of false and misleading advertising statements violate FD&C Act § 502(a)(1) [21 U.S.C. § 352(a)(1)] because they, “fail to reveal facts material in light of such representations or material with respect to the consequences which may result from the use of the article to which the labeling or advertising relates under the condition of use prescribed in the labeling or advertising thereof.” FD&C Act § 201(n) [21 U.S.C. § 321(n)]. They also violate FD&C Act § 502(q)(1) [21 U.S.C. § 352(q)(1)] because the advertising for the aligner, a restricted device, was false and misleading.

a. The impression kit route to obtaining SDC aligners

SDC sells “New Smile Kits” in retail stores including Macy’s, CVS, and Bed Bath and Beyond that customers must register with SDC. It also sells kits directly to consumers on its website, in which case the kits “come preregistered.” [Exhibit 18, SDC document] These kits are cube shaped boxes containing on their exteriors large print marketing language and photos. [Exhibit 19, picture of a portion of a “New Smile Kit”] On the upper right hand corner of one side of the box “rx” appears in very small print, especially when compared to the other printing on the box. [Exhibit 20, picture of side of box with “rx” in corner] The kits are shipped to customers or purchased at point of sale with no waiting time or prescription required. [Exhibit 12, ¶¶ 12, 13] “New Smile Kits” contain a number of items, including three sizes of impression trays “for sizing”, a “premium whitening pen”, lip balm, “a Smile Stretcher for photos”, and *New smile guide* booklet [Exhibit 21, SDC booklet], and a registration card. [Exhibit 22, SDC Registration Card] There is also promotional material for a tooth whitening light that can be plugged into a cell phone, for use with the “premium whitening pen”.

Once the customer sends in the registration card with his or her best guess as to the size impression tray he or she needs, the Smile kit becomes “registered” and the customer receives by overnight delivery the SDC Impression Kit comprising the impression material and the actual impression trays provided in the size designated by the customer. [Exhibit 23, screen grab of SDC Impression Kit website page.] The registration card includes the extremely misleading statement that the impression material is being sent, “on your doctor’s behalf.” The SDC “affiliated dentist” who is allegedly “assigned to oversee [the customer’s] smile” [Exhibit 22] and on “whose behalf” the impression kit is sent, knows nothing about the customer, and certainly has no information needed to write a legitimate prescription.



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After mixing the two-component “putty”, the customer loads it into the trays and makes two impressions each of his or her upper and lower teeth.<sup>15</sup> The upper impression tray does not include the portion needed for taking an impression of the customer’s palate. This renders the tray incomplete because a palate impression is an important tool used to properly register the molds of the upper and lower bites with each other and helps in determining the nature and full extent of an individual’s orthodontic issues. [Exhibit 5 ¶¶ 23] The SDC customer’s amateur mouth photographs (see, *infra*), may fail to reveal the extent of the problem or its existence at all. [id.]

At the same time the customer provides SDC with the impressions, she or he must upload photos, taken by cell phone or other camera, of the customer’s mouth. Instructions on how to use the Smile Stretcher for this activity are included in the *New smile guide* booklet. [Exhibit 21, pp. 10-13; Photocopy of Smile Stretcher device, Exhibit 24]

As Dr. Markarian explains, it is difficult for a trained, experienced professional to make good dental impressions of a patient’s teeth even in the controlled environment of an office equipped to take and retake such impressions, and it is important to be able to see and examine the patient while the impressions are being taken. [Exhibit 5, ¶¶ 19, 20] In addition, there is the possibility that a person will experience an allergic reaction to the impression material, sometimes serious enough to require medical intervention. If a person suffers an allergic reaction, or gagging, or choking while trying to self-take his or her own dental impression, the quality of the impression will likely be compromised and either have to be taken again somehow, or an alternative method will have to be used. [Exhibit 5, ¶¶ 21, 22]

As for the required customer taken photos, because of lighting issues, the photographer’s lack of skill, and the fact that the photos cannot be compared to the live customer either in person or via a suitable teledentistry platform, they are almost inherently of little clinical value. For example, they may not properly show the position and alignment of the customer’s molars, which should be a major factor in determining whether to provide a customer with SDC plastic aligners, which only move front teeth. Customers are likely to take misleading, unrevealing

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<sup>15</sup> Since the “affiliated dentist” assigned to “oversee” the customer’s “new smile” never actually sees or talks to the customer, not even via SDC’s purported “teledentistry platform,” one wonders how SDC knows which impressions to choose for manufacturing the aligners.

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photos, in spite of SDC's brief instructions to the customer on the subject. Even experienced dentists can have issues evaluating photos they have taken in their offices using special equipment, which is why access to other information and to the patient is so important. [Exhibit 5, ¶ 24]

For those customers who choose the "make your own dental impression route" the steps described above comprise the sum total of the "examination" the customer undergoes prior to receiving SDC's "clear aligner therapy treatment". There is virtually no information provided to SDC from which an informed, valid prescription for orthodontic treatment can be written.

b. SDC's "SmileShops" route to obtaining SDC aligners

SDC also sells its plastic aligners through its "SmileShops". These are brick and mortar locations where customers have their mouths scanned by SDC "SmileGuides" using 3D hand-held scanners, which provide the digital equivalent of a physical dental impression. SDC promotional literature clearly shows that, just like SDC's incomplete upper impression trays, its scans do not provide any information about the state of a customer's palate. [Exhibit 25, post from SDC's Instagram page]

It is unclear what level of training or expertise the "SmileGuides" have, but SDC represents that at least some are dental assistants or dental hygienists. The SmileGuides also take photos of the customers' mouths.

Scans and photos, just like impressions and photos, can be two valuable tools used in the fabrication of plastic aligners. Looking at them does not constitute an orthodontic examination, however, and provides very little, if any, reliable information about a patient's underlying oral health. Writing prescriptions, if that is really even done, on the basis of such insufficient medical information is a sham.

#### **4. SDC's Business Model Does Not Include the Use of Valid Teledentistry**

SDC tells its customers that they are served through teledentistry. [See, e.g., Exhibit 21, p. 8, Exhibit 22] Photos and scans are reportedly uploaded and sent electronically to SDC for alleged review by "affiliated dentists", and aligners are produced and sent to the customer as a result. That seems to be pretty much it. No doctor-patient interaction takes place. Customers are not



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required to upload or otherwise provide their existing dental records and, of course, there is absolutely no dental examination, remote or otherwise, conducted by the SDC affiliated dentists.<sup>16</sup> SDC never states that it provides environments where true teledentistry can be conducted because it doesn't provide them and the company does not claim that the "affiliated dentists" do either. What SDC does is not valid teledentistry first and foremost because it is not valid dentistry.

Without a doubt, sufficiently robust teledentistry platforms make it possible to expand patient access to quality care. Petitioner's support for safe and effective teledentistry modalities is one of its Current Policies. [Exhibit 26, Comprehensive ADA Policy Statement on Teledentistry, Current Policies, Adopted 1954-2018] Included among the important elements of an acceptable telehealth platform, but which are not part of what SDC offers, is "live, two-way interaction between a person (patient, caregiver, or provider) and a provider using audiovisual telecommunications." It should also require that patient dental records be furnished for review over a secure system.

The ADA policy points out that:

The dentist is responsible for, and retains the authority for ensuring, the safety and quality of services provided to patients using teledentistry technologies and methods. **Services delivered via teledentistry should be consistent with in-person services,** and the delivery of services utilizing these modalities must abide by laws addressing privacy and security of a patient's dental/medical information. [Emphasis added]<sup>17</sup>

SDC's claims that it serves customers through "teledentistry" cannot paper over the non-existent orthodontic examination and care its customers receive from SDC's "affiliated dentists." They do not interact with customers in real time or in any other way despite SDC representations to customers that they are able to "chat with your dental team whenever you'd like."

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<sup>16</sup> Petitioner knows of exactly *one* (1) instance where a patient's general dentist was asked to clear him for SDC aligners.

<sup>17</sup> The ADA Policy supporting teledentistry is consistent with the views of both the U.S. Federal Trade Commission (see, e.g., 8/3/16 FTC Opinion Letter to Delaware Board of Occupational Therapy Practice) and U.S. Department of Justice (see, e.g., 11/29/16 Opinion Letter from the DOJ Antitrust Division to Senator Peter MacGregor, Michigan State Senate).



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What SDC means by “chatting with your dental team” is engaging in on-line exchanges with SDC’s customer services department or social media team. The responses often appear to be automated and sometimes extremely frustrating. [Exhibit 27, 4/5/19 exchange on SDC website between customer Jessica Cheaves and SDC’s “dental team”]

Customer “chats” included here confirm that: a) customer dental exams are not conducted by the affiliated dentists; b) submission of dental records to the affiliated dentists is not required in order to buy aligners from SDC; and, c) customers deal almost exclusively with sales representatives or marketing teams and not dentists in connection with their SDC “treatment.” [Exhibit 28, 1/28/19 Yelp Review by ZY reporting that his wisdom teeth erupted during treatment and SDC response; Exhibit 29, 4/6/19 Facebook post by Myhoa Tran showing ill fit of aligners and efforts at resolution; Exhibit 30, 2/5/19 Yelp Review by Garrett F. concerning dental issues and SDC response; Exhibit 31, Facebook post 4/11/19 by Nicholas Stevens about treatment problems and SDC response]<sup>18</sup>

Of course, doctor-patient interactions would not occur on public forums, but there is no indication that the social media team’s invitation to “please send us a private message” ever leads to a dentist-patient interaction. This is consistent with SDC’s business model. If SDC actually did provide a teledentistry platform the patient could make an appointment with the “dentist assigned to your smile” and not have to post on social media at all.

#### **5. SDC’s “Consent and History” Form is an Attempt to Disclaim Liability for Failing to Conduct a Patient Exam that Approaches the Standard of Care**

As members of a learned profession, dentists are bound by ethical considerations and duties that are not generally imposed on commercial enterprises. It is their professional responsibility to satisfy themselves with sufficient evidence and information that the treatments they are prescribing for their patients are appropriate and safe. In order to make this determination they can review patient records compiled by other dentists and they should conduct their own patient examination as well.

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<sup>18</sup> Petitioner acknowledges that SDC also receives positive customer reviews.

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SDC and its affiliated dentists do not follow this approach, and perhaps the most damning evidence disproving SDC's advertising claim that its customers get the "same level of care from a [SDC] treating dentist or orthodontist as an individual visiting a traditional orthodontist or dentist for treatment" [Exhibit 14], is its own Consent and History form that it makes customers sign. Instead of conducting a competent orthodontic exam SDC affiliated dentists rely on customer self-reporting. The form provides that:

By signing this Informed Consent, I understand that I am certifying that:  
My dentist cleaned my teeth. My dentist took x-rays of my teeth. My dentist checked for and repaired cavities, loose or defective fillings, crowns or bridges. My dentist checked my x-rays and I have no shortened or resorbed roots. My dentist checked my x-rays and I have no impacted teeth. My dentist has probed or measured my gum pockets and says I do not have periodontal or gum disease. My dentist preformed a full oral-cancer screening in the last 6 months and I do not have oral cancer. I have no pain in any of my teeth. I have no pain in my jaws. I have no loose teeth. I have no "baby teeth" and all of my permanent teeth are present.

[Exhibit 13, pp. 3-4] This self-certification is SDC's and the affiliated dentists' substitute for an exam. The customer is not asked to produce any of these records or any other evidence of oral health. Lay self-reporting does not meet the examination Standard of Care for writing a prescription for orthodontic treatment. Lay people are not expected to be familiar with specialized technical or medical vocabularies. Some may think that "periodontal" refers to a type of flying dinosaur.

Apparently, however, SDC and the affiliated dentists believe they are professionally off the hook once the customer signs the form. Dr. Burriss explained in his Q & A's that one of the things that really impressed him about SDS's business is, "how brilliant and **legal** it was..." [Emphasis added] [Exhibit 15, Q&A #1] The following shows how important Dr. Burriss considers the Consent form:

12. What would you say we have to be most vigilant about, knowing we don't see a dentist in person specifically about the aligners? What would be the red flags to look out for?

1. **Well first, every SDC patient signs a document** saying they are under the care of a dentist and I'd recommend cleaning and checkups every 6 months or every three months while in treatment just like I do with in office patients...Look, this isn't rocket science or brain surgery this is just moving teeth. Teeth move on their own

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all the time and despite all the fearmongering from dentists and orthodontists trying to scare people out of SDC **"there is very little that can go wrong if you are honest on your health history** and keep your teeth clean." [Emphasis added]

[Exhibit 15, Q&A #12]

The Question contains an unambiguous statement that customers are not examined by SDC affiliated dentists (whether face-to-face or via teledentistry), and the Answer includes the admission that SDC affiliated dentists don't review any customer dental records. So how can they write a professionally valid prescription for orthodontic treatment? They can't.

The SDC affiliated dentists don't get paid much. In 2017 this exchange took place with Dr. Burris:

Q. I have one nagging question. Do you have a financial interest as an investor in SDC?

A. Yup. I get paid 50 whole dollars **for each case that I approve** and the customer accepts (buys) just like every other ELP! ... [emphasis added]

[Exhibit 15, unnumbered Q&A, p.9). It is disappointing, but perhaps not surprising, that the SDC affiliated dentists may not endeavor to meet the standard of care because of the small amount of money they make on a per customer basis. What is shocking is that they only get paid if they "approve treatment" (n.b., he doesn't say "prescribe treatment"). This presents a conflict of interest, suggesting the possibility that treatments are being approved that should not be. The affiliated dentists also have the incentive to spend as little time as possible on each case in order to maximize their "approval" volume. This is consistent with the no-exam/patient self-certify model SDC has chosen.

One other aspect of the form helps to illustrate SDC's approach to its customers. Although it is not directly related to the violations by SDC of the FDA's "by prescription" restriction, it is telling. Specifically, the form includes a section titled in bold, large type, "AGREEMENT TO ARBITRATE". This provision appears to provide recourse to customers who believe they have an actionable dispute against the company or the affiliated dentists. [Exhibit 13, p. 3] But, in the second to that last paragraph of the document, which otherwise seems to be exclusively



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directed to a photo release, appears the following sentence, tucked into the middle of the paragraph:

I release SmileDirectClub from liability or any claims by me or any third party in connection with my participation or use of the invisible aligner therapy treatment.

[Exhibit 13, p. 4] This blanket waiver, hidden in a photo release, is an attempt to bar actions against even malpractice, which is prohibited virtually everywhere. Physicians and dentists cannot shirk their duty to their patients to meet the applicable standard of care and then escape the consequences by disclaiming liability through use of an illegal contract provision. But SDC, in small print, tries to do just that and may be counting on the fact that their customers will be fooled.

Whereas the motto of the health professions is, “first, do no harm,” it is apparent from SDC’s “Consent and History” form that SDC’s motto is “buyer beware.” That is not acceptable in the healthcare arena.

### **CONCLUSION**

SDC’s process for providing teeth aligners to its customers to correct malocclusion falls far short of even the most minimally acceptable standard of care. It is so woefully deficient in this regard that any putative “prescriptions” generated as part of its customer transactions are no more than technical formalities without medical support or basis. They are pretexts, mere fig leaves intended to hide the company’s substantial, knowing non-compliance with the pertinent labeling and safety laws.

The instant Petition is submitted in an effort to vindicate important regulatory principles, namely, that it is a serious violation of the law for a company distributing a restricted Class II medical device in interstate commerce to use false and misleading statements to entice consumers and to skirt restricted device prohibitions by declaring technical compliance with the statutes and regulations without substantive compliance. Enforcement against SDC will deter others in the industry from engaging in the same or similar conduct as SDC.

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### **C. ENVIRONMENTAL IMPACT**

The action(s) requested are categorically excluded from the requirement to provide an Environmental Assessment or Environmental Impact Statement under 21 C.F.R. §§ 25.30(a)-(d).

### **D. ECONOMIC IMPACT**

It is our understanding that detailed information on this subject is to be submitted only when requested by the Commissioner following review of the petition.

### **E. CERTIFICATION**

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

American Dental Association  
211 East Chicago Avenue  
Chicago, IL 60610  
312-440-2500

If you have any questions, please contact Mr. C. Michael Kendall, Sr. Associate General Counsel, at 312-440-2810 or [kendallc@ada.org](mailto:kendallc@ada.org).

Sincerely,

/s/

Jeffrey M. Cole, D.D.S., M.B.A., F.A.G.D.  
President

/s/

Kathleen T. O'Loughlin, D.M.D., M.P.H.  
Executive Director

/s/

Marcelo Araujo, D.D.S., M.S., Ph.D.  
Vice President, Science Institute

# Exhibit 9

[Member Login \(https://orthopundit.com/members/\)](https://orthopundit.com/members/)

BEN THERE

**DR. BEN BURRIS**

DONE THAT

[\(https://orthopundit.com/\)](https://orthopundit.com/)

## Q & A With the Largest SmileDirectClub Facebook Group



📅 05/13/2017 (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/>)

👤 admin (<https://orthopundit.com/author/admin/>)

I was asked by the admin of the largest SmileDirectClub users' group on Facebook if I'd take questions from SDC patients and potential patients. Of course I was happy to oblige. Below is the result:

Questions for Dr. Ben Burris compiled by Allyson Miller (<https://www.facebook.com/bunnieskill>) from questions asked by SmileDirectClub users in her group, Smile Direct Club Members Forum (<https://www.facebook.com/groups/sdcsupport/>)

\*\*\*\*\* My answers to these questions are my own. I am an ELP for Smile Direct Club and I serve on the Clinical Advisory Board but I have no official position with SDC beyond that. I'm giving my professional opinion based on my experiences and what I have done in my offices as well as what I've done for SDC patients. \*\*\*\*\*

**1. How did you first learn of Smile Direct Club and become involved with them? Did you have any skepticism initially?**

1. Of course I was skeptical – I'm an orthodontist after all. The first time I ever heard of SDC was on Facebook. I saw the ad and I commented saying, "You can't do that. That's practicing dentistry. How are you getting around that?" The SDC team replied and explained their model and their history of going direct to consumer in other industries and I was intrigued. That led to further discussion and once I realized how successful SDC would be and how brilliant and legal it was, I wanted to be part of SDC. I spent a lot of my time trying to convince orthodontists that SDC is a good idea because I could see what would happen in the industry in the future and truly wanted orthodontists to have a hand in making access to orthodontic care widespread. I told orthodontists that they should get involved with SDC so they would have their foot in the door and could see how this whole teledentistry thing would play out. I failed miserably but I tried. Once Invisalign invested in SDC some orthodontists became interested and wanted to get involved but that ship had sailed. I used to beat myself up for not thinking of/inventing an SDC model myself but realistically I think it would be impossible for any orthodontist to get that far out of our little boxes to envision such a radical model. I'm just glad to be part of that.

**2. How do you see the future of teledentistry? Do you envision a service level that might include some limited in-office care but still have reduced overhead for the treating orthodontist, maybe an SDC program that includes attachments, for example?**

1. I would never do an SDC model that includes attachments or IPR. Once you go there it's an entirely different animal. As human beings, that's the temptation – to just do a little more... but I believe that trying to have it both ways will become a morass for the patients and the doctors. I am sure there will be some "limited" treatment models in orthodontic offices and they will be successful to the degree that they can set and deliver on patient expectations. The issue there is that most patients want full service while paying for carry out. This is part of the human condition and we are almost all guilty of this to some degree. I certainly will continue to reduce the price of treatment in my office and offer less involved treatment options as I've done for years. It will be interesting to see how this plays out.

**3. You believe that teledentistry is going to be an imminent part of the future of orthodontics. SDC has had wildly successful growth within the last year, but this has resulted in some pretty significant growing pains for the company. Do you think they will be able to push through this and iron out the issues, or will it result in their demise as a company? What kind of advice would you have for a company experiencing growth issues like this?**

1. I've said it for over a year now – in 3 years SDC will be treating more orthodontic patients than all the orthodontists in the US combined. I stand by that prediction. Of course I'm not a prophet so I



may not be 100% accurate but I'll be close. These guys have done direct to consumer in other, more invasive, more heavily regulated spaces and they will have no problem delivering an elective service like simple tooth movement. Every business has a learning curve and one like SDC certainly does but the creators are brilliant and they have a great team. My advice to those who don't believe is to hide and watch SDC deliver!

**4. Have you seen a change in attitude amongst your colleagues in regards to SDC since it first began until now? Are orthos/dentists being more receptive to the idea? Or is there more resistance? In general.**

1. Most orthodontists hate SDC. Literally hate it. Much the same way that coal miners hate solar and wind power I assume. Think about what you do for a living and how you'd feel if someone outsourced your job or company to robots or overseas. Even if it's good for everyone else in the country, you'd be at least a little upset. This is how orthodontists perceive SDC. Now, that doesn't make their position correct as I've stated many, many times on OrthoPundit.com. A few have seen the light and have a new appreciation for SDC but most have not changed. I think the biggest impact on orthodontists will be a general lowering of fees over time as I've discussed.

**5. We are familiar with two different SDC plans: 1) the traditional 2-week plan where aligners of similar thickness are worn for two weeks each, 2) the "1wk/1wk/2wk" plan which has three aligners per month of progressive thickness. Both are actively prescribed. Can you give a little insight on the discrepancy between plans? Is this up to the doctor working on a particular case or the technician who draws up the plans for the doctors?**

1. The difference is in the manufacturing process. Some aligners are produced by Invisalign and some by SDC's Smile Lab. Both are effective and play to the strengths of their materials.

**6. What is the criteria for being approved for SDC? (What cases do you turn away?)**

1. I can't tell you what other ELPs do but I can tell you what I'll approve and what I won't. First, I'll reject any case where there are apparent or suspected periodontal issues, calculus buildup or cavities. I understand that a great many laypeople think they can just say they've had a cleaning and a checkup and that I won't be able to tell the difference but this is what I do for a living! It's much better for the patient to actually get a cleaning and checkup instead of just saying they have – especially if they have less than ideal oral hygiene. It saves everyone time and effort. Next I'll reject any case where I don't think we can get significant improvement for the patient and cases where I feel that treatment is detrimental to the patient. I don't have to think we can get perfection to approve a case but I want to see a significant improvement. All told, I reject a relatively small amount of cases that make it to me for evaluation so the odds are great that if you have clean teeth, no periodontal disease and no cavities that you'll be eligible for treatment. Other things to avoid when submitting your case for treatment are bad photos (dark or out of focus or too far away – as long as I can see the teeth and gums in focus then they are good enough and they don't have to be perfect), forgetting to fill out or sign your health history form and consent or leaving partial dentures in for photos. I can't move teeth that have a partial denture (because the partial won't fit) and I can't move teeth that have a bonded retainer on them. The best way to find out if you qualify is to get the kit and submit your case.

**7. What are the differences between Invisalign and SDC? Why does Invisalign use the "bumps" on the tooth?**

1. The bumps are called attachments and they are designed to give the orthodontist specific control over tooth specific tooth movements. SDC doesn't use these because they must be applied in an office setting. As I mentioned before SDC and in office treatment are totally different things and I would oppose trying to do attachments with SDC.
8. **How effective do you think SDC's aligners are at complicated movements like rotations without attachments like Invisalign has? Is there truth to the rumor that the straight gum edge provides extra leverage and minimizes (in any way) the need for attachments?**
  1. SDC has a great product and I've been pleasantly surprised by how effective SDC's trays are at moving teeth and getting great improvement. That being said, rotating round teeth is difficult with and without attachments (and in the office as well as via teledentistry). SDC's goal is to get patients a smile they can be proud of. In most cases that's an awesome, straight smile but even in the cases where we can't fully align the teeth, SDC makes the smile much better and people are very happy. People who have crazy crooked teeth and want "perfection" should see an orthodontist. People with crooked teeth who want them straighter and looking great should consider SDC. I would also mention that Invisalign obviously believes in the efficacy of SDC and their aligners and put their money where their mouth is.
9. **Many people have been told that SDC cannot move molars, but many plans show them doing just that. Why the discrepancy?**
  1. SDC doesn't typically move molars or even premolars but occasionally, especially on the lower, the molars and premolars will be angled toward the tongue and lend themselves to some tipping during treatment.
10. **How is it determined if a person would benefit from IPR, and why do you think SDC stopped offering it? How will this affect treatment for some?**
  1. SDC doesn't do IPR any longer, thankfully. IPR is a great procedure but the logistics involved don't lend themselves to offering IPR with SDC.
11. **How much involvement and oversight do the SDC orthodontists have on our cases? Do the dental professionals who oversee our cases look at our photos, or just impressions/scans? Who makes the occasional requests for X-rays?**
  1. I can't speak for others but I assume they do it similarly to me. I look at every case in the beginning – photos, health history, consent, chief complaint, models and treatment setup – and decide if the patient is a candidate. Once I determine a patient is healthy enough for treatment I decide on the treatment plan and I make refinements with the setup team as needed. I also see photos from patients with questions and when we do refinements or mid-course corrections. I'm very picky about the photos and the history and consent and need to see what I need to see before I'll evaluate and/or approve a case and I require follow up photos so I can follow the patient through retention. As to the question about x-rays, I'll ask for a panoramic x-ray occasionally – especially when I suspect impacted teeth or unreported implants/dental work.
12. **What would you say we have to be most vigilant about, knowing we don't see a dentist in person specifically about the aligners? What would be the red flags to look out for?**
  1. Well first, every SDC patient signs a document saying they are under the care of a dentist and I'd recommend cleanings and checkups every 6 months or even every 3 months while in treatment just like I do with in office patients. Next, oral hygiene is the most important thing you can do. Brushing

and flossing is the best way to stay out of trouble. Finally I'd recommend that if you have a question about anything, take a photo and send it to SDC and they will have your doctor look at it. Look, this isn't rocket science or brain surgery this is just moving teeth. Teeth move on their own all the time and despite all the fearmongering from dentists and orthodontists trying to scare people out of SDC there is very little that can go wrong if you are honest on your health history and keep your teeth clean. Adult patients will feel like their "bite is off" for a while because any change feels weird but this is elective, non-invasive treatment that has the goal of making your smile better and there is very little that can go wrong. Also remember that sometimes things go wrong in traditional offices as well as in SDC cases. That's life. The only way to avoid issues with your teeth is to avoid doing any treatment... NOT! You may have issues with your teeth without treatment so it's just part of life we have to accept.

**13. (Related) What signs should I look for to know if I need midcourse correction?**

1. Every case is different. If you have a question then take a photo and send it in so your doctor can take a look at is my advice.

**14. How many people have or are currently using SDC?**

1. I don't know but it's a lot!

**15. (From a customer who has dealt with uncommonly severe service and quality-control issues.) Are the doctors made aware of deviations in the prescribed treatment plans caused by quality-control problems at SDC's manufacturing facility? For example, a patient is sent Month 1 aligners three, four, or more times in a row (although they are incorrectly "labeled" Month 2, 3, etc.) and the (unknowing) patient proceeds to re-complete Month 1 treatment multiple times. When the patient realizes the mistake and requests to communicate with the doctor overseeing their case, the request is ignored, and SDC directs the patient to continue on with treatment. So once again, my question is, is SDC notifying the doctors of these deviations in treatment?**

1. As with any human endeavor, human error is a part of it. Sounds like you've had bad luck and I'm sure SDC will take good care of you and this will get sorted out. The thing to remember is that this kind of snowballing human error can happen in my traditional office just as easily as it can with SDC. It's just life. And it happens in every dental office across the country and around the world from time to time. The key is to ask questions if you have questions and keep asking them. I am notified of any and all issues my SDC patients have and I do my best to take great care of everyone but I'm human just like everyone else! I'm sorry you've had issues but luckily this is not brain surgery and it still beats having to go to the office very 4 weeks!

**16. Last year SDC was recommending that we wear retainers for six months full-time after the end of treatment before switching to nightly wear for life. Now they recommend only two weeks of full-time wear. That is a big reduction. In your opinion, how long should we ideally wear retainers full-time after treatment? I've been wearing my last tray for about 6 weeks while waiting for my refinements to come in, and if I leave them out for more than an hour they are tight again, so how could I move to night wear only after 2 weeks?**

1. Funny you bring this up – it was my suggestion to the company to reduce the full-time wear to two weeks followed by lifetime nighttime wear! That's what I did in my practices. The trick with retainers is that if they ever start to feel tight, increase the amount of wear until they don't feel tight when you put them in.

- 17. We are aware of at least three retainer types: 1) SDC clear retainers, 2) Hawley (wire and acrylic) retainers, 3) Permanent bonded retainers (lingual bar). Would you recommend any of these over the others?**
1. In my offices I used clear, form fitting retainers like SDC uses. Many moons ago, I used to make my own Hawley retainers by hand – they were really fancy and were the “wrap around Hawley” variety because we orthodontists believe that more complicated means better. It’s just not the case. I also used to do a lot of bonded retainers but I don’t recommend them anymore because people can’t floss around them and I’d see cases years later with periodontal disease and cavities under the bonded retainer.
- 18. SDC recommends that only cool water be drunk while wearing aligners, but some unaffiliated orthodontists have told Invisalign patients it’s fine to drink other beverages as long as they rinse, brush, and clean the aligners soon after. Our forum is in conflict! What are your thoughts on this?**
1. SDC knows the composition of their aligners better than I do so I would recommend following their recommendations.
- 19. Many members file their aligners to improve comfort and to “customize” them. How much overhang beyond the gum line should stay intact for the aligners to still be effective? Some people have filed away coverage of the molars, reasoning that those teeth are not being moved. Is this a good practice?**
1. Altering the aligners slightly to make them comfortable is certainly ok. If you go beyond that then you risk negating the efficacy of the aligners. How much is too much would be a case by case assessment but I would advise against major modification. Cutting the molars off can cause you to develop an open bite so I would certainly advise against that.
- 20. This question is about the importance of contiguous wear versus total hours. How many consecutive hours is “too many” to have your aligners out? We have heard from people who are not making their daily hours but who attempt to make up for it by tacking days on to the end of each aligner. At what point is this ineffective?**
1. In my experience, simplicity is the best way to get the results you want. Make it too complicated and you will likely fail. I advise that you wear your aligners all the time except while eating and brushing and you’ll likely get the results you want. Deviate far from that and your results can be questionable. How much is too much? Impossible to tell but either you get the results you want or you don’t. In my experience the VAST majority of cases that don’t get results come from not wearing aligners – either in my office or via SDC.
- 21. What if I like my results before I’m fully done with my treatment? Can I just request a retainer at that time, or would the orthodontist/SDC not do it because I didn’t follow the treatment plan? (I have seen a few people with great results early on and would love to have quick results like that.)**
1. If you are happy, of course you can ask for the treatment to stop at tray # whatever. If you want that then keep wearing the tray that makes you happy, don’t move on to the next one, take a couple photos, contact your SDC representative and make a plan with your doctor. I’ve had many patients under my supervision do this. IF YOU HAVE A QUESTION ABOUT YOUR CASE, CONTACT SDC SO YOUR DOCTOR CAN LOOK AT YOUR CASE!! J
- 22. In my search for a permanent retainer post-SDC, I found many orthodontists were hesitant to provide one (even a Hawley, not permanent bonded) even without the mention of having done teledentistry treatment. Why would this be? The ortho I finally found to place one charged me \$150 (I would have**

paid more!) and he was in my mouth for <15 minutes; I left with a 3 cm piece of wire and four cement globs. Just curious why there's such hesitation when that seemed to be a pretty profitable appointment.

1. I'm as liberal and understanding as they come as far as orthodontists go but I won't put a bonded retainer on a case that someone else has treated or even repair a bonded retainer that's not mine by and large. I don't because I learned the hard way that if I do then if anything goes wrong with the case then it's all my fault in the eyes of the patient (unrealistic and illogical but the way it is). It's just not worth it even at 500 bucks per bonded retainer. Also, as I mentioned before I don't recommend bonded retainers any more.

**23. I got an email to order retainers. I am on 15 of 20 trays, so how would SDC know that my teeth will be done/perfect for retainers so soon before 19 or 20 trays?**

1. With excellent wear and good tracking, aligner treatment is very predictable. If it doesn't work out (as life occasionally does not) then SDC and your doctor will make a new plan

**24. Can I get fillings during treatment? Are there associated risks?**


1. I would not recommend it because it may change the shape of the teeth so that the aligners don't fit. It's far better to get your dental work done before SDC treatment and that's why you sign a form saying you have no pending dental work.

**25. Is it normal for your bite to be off three quarters of the way through treatment (Tray 8 of 12)?**

1. As mentioned earlier, almost all adults feel "their bite is off" early in treatment. This is normal and expected since we are moving the teeth. This is evaluated on a case by case basis so take a photo and contact SDC if you have a question so your doctor can look at it.

**26. BONUS CONTENT: Comments from a discussion about how much patients wear their aligners:**

1. Patients wanting 100 percent results without doing their part 100 percent are the bane of my existence. I'm fine with a lack of cooperation and compliance as long as patients are fine with a lack of results! Many patients complain about and try to minimize aligner wear but there is a limit to convenience and doing the minimum while still getting results. People have to be reasonable and if they do the minimum they must be ok with minimal results. There is a disconnect between a lack of aligner wear and a lack of results. Aligners don't work if you don't wear them!  
(<https://orthopundit.com/new-study-proves-clear-aligner-therapy-totally-ineffective/>) The amount of time that you wear aligners is the only variable you have control over as a patient. Not wearing them all the time except for brushing and eating is just plain crazy to me. You spent all this time and money and you don't do everything you can to get a good result and then you expect the aligners and the doctors to fix that? It just doesn't make sense.

orthodontists (<https://orthopundit.com/tag/orthodontists/>), retainer (<https://orthopundit.com/tag/retainer/>), SmileDirectClub (<https://orthopundit.com/tag/smiledirectclub/>), smiledirectclub members forum (<https://orthopundit.com/tag/smiledirectclub-members-forum/>)  Permalink (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/>)

## 13 thoughts on “Q & A With the Largest SmileDirectClub Facebook Group”

**Thomas Gessel on 05/17/2017 (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/#comment-3518>)**

I have one nagging question. Do you have a financial interest as an investor in SDC?

Reply (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/?replytocom=3518#respond>)

**admin on 05/17/2017 (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/#comment-3519>)**

Yup. I get paid 50 whole dollars for each case that I approve and the customer accepts (buys) just like every other ELP! My question to you and other orthodontists is do you have a financial interest in being anti-SDC? I seem to remember that you and almost all the other orthodontists turned your noses up at 50 bucks as “not worth your time” when I was trying to convince you all to sign up as an ELP...

Reply (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/?replytocom=3519#respond>)

**Thomas Gessel on 05/22/2017 (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/#comment-3568>)**

My question was more about financial interest as a shareholder, not a provider. I listen closely to your advice, but, like my financial advisor, I like to know the financial relationship of the person providing advice.

Reply (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/?replytocom=3568#respond>)

**admin on 05/22/2017 (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/#comment-3570>)**

I don't own any stock. I hope to in the future. I'm sure I'm not the only orthodontist who hopes to. Many, many orthodontists have asked me how they can get a piece. It's been funny to watch orthodontists clamor for ELP positions and a chance to buy into SDC ever since align bought in. It's even funnier to watch how they redouble their efforts to defame SDC when they are denied.

I'll ask you again. Do you and other orthodontists have any financial interest in being anti-SDC?? I think you do. I know you do. You were all too proud and knew better when the door to get involved was open and now you're shut out and pissed. By the way, why is it that you only ask people if they have ownership in things you don't like



or agree with but swallow whole the sales pitches of all those traditional orthodontists that you admire while they shamelessly hock their wares? The AAO even did away with speaker disclosures at the annual session!!! I guess it's ok to have ownership in a bracket or piece of software while selling it? You guys are too funny.

Reply (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/?replytocom=3570#respond>)

**Thomas Gessel on 05/26/2017 (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/#comment-3579>)**

Thanks for the disclosure. It really does help me know the motivations behind advocating for a product or service. I think the AAO screwed up by doing away with disclosures. If I'm at a Henry Schein meeting or Damon forum, I assume I'm going to see a marketing pitch with clinical pearls mixed in. When I'm at the AAO, I hope I'd receive more science-driven presentations. Maybe it's naive to expect that, but that is my hope.

I haven't signed up for SDC because my time is completely occupied by my clinic, family, and hobbies. I barely have time to review clin-checks. I don't think it's a bad thing; I just prefer to see patients face-to-face (they like my face).

**admin on 05/22/2017 (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/#comment-3571>)**

By the way I don't own any align stock either.

Reply (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/?replytocom=3571#respond>)

**Thomas Gessel on 05/26/2017 (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/#comment-3580>)**

Either do I. I don't own any stock. Scares me to give up control/buy something I don't completely understand.

**Marc Ackerman on 05/17/2017 (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/#comment-3521>)**

I think the most demonstrative point of your piece is that there are a large number of SDC users and they are organized on social media. I don't know of any lay public FB group that exists for self-ligated bracket consumers or custom lingual bracket consumers or for that matter any traditional orthodontic "system". If I'm correct, than it should be a real wake-up call to the orthodontic community!

Reply (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/?replytocom=3521#respond>)

**admin on 05/17/2017 (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/#comment-3522>)**

Awesome point.

Reply (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/?replytocom=3522#respond>)

**Vanessa on 06/26/2018 (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/#comment-4742>)**

This was very educational. I am days away from my new grin. I was disappointed to learn i would have to pay for the retainer and wear it forever. I shopped around before SDC and some orthodontists wanted to remove teeth, i though NO WAY! When i told my dentist that i started SDC i got the side eye. I think its ridiculous to pay 5,000 for braces or invisalign especially since my treatment was only for 5 months. I cant wait to get my teeth cleaned and show off my new smile.

Reply (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/?replytocom=4742#respond>)

**admin on 06/26/2018 (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/#comment-4743>)**

Good for you. Retention is a part of life and you only need to wear your retainer as long as you want your teeth straight! 😊

Reply (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/?replytocom=4743#respond>)

**Robin Bethell (<http://forestfamily.com>) on 10/29/2018 (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/#comment-5059>)**

This Discussion was fantastic. I am impressed by your forethought and objectivity, Dr. Burris. I am a faculty for Align, a General Dentist, and Diamond Plus provider. When I first understood SDC (May of 2017) I predicted that the market for clear aligners would expand %500 by 2020 (I have witnesses!). Without SDC publishing sales it is hard to know officially if that is happening, but in the last 24 months Align's shipped cases have gone up over %100. Forums like this one show how excited the Average American is for SDC. Though I have seen some minorly tragic results from SDC in my office (gum recession, POBs, absolutely impossible plans), I feel we have a responsibility to help our patients. If I was asked, I would be an ELP. When my patients embarrassingly tell me they are trying SDC I ask them how it is going and offer support. Vanessa's experience with the "side eye" is all too common, and will scar our profession.

All in all I think you are on the right side of history here, and I'd love the opportunity to learn from you and assist you in any way I can. Thank you for making this post public. 😊

Reply (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/?replytocom=5059#respond>)

**admin on 10/30/2018 (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/#comment-5070>)**



Thanks, I think? I will never understand the claims that you've found a few cases that you think didn't finish well with DTC proves that it's bad. I've seen literally thousands of cases that didn't work out – from dentists, from orthodontists and from myself. We all have cases that don't work out and I'd be willing to bet that as a percentage direct to consumer tx with aligners has less problems and less complaints than traditional offices – dental or orthodontic. <https://orthopundit.com/its-dty-not-diy/> (<https://orthopundit.com/its-dty-not-diy/>)

Reply (<https://orthopundit.com/q-a-with-the-largest-smiledirectclub-facebook-group/?replytocom=5070#respond>)

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- › August 2018 (<https://orthopundit.com/2018/08/>)
- › July 2018 (<https://orthopundit.com/2018/07/>)
- › June 2018 (<https://orthopundit.com/2018/06/>)
- › May 2018 (<https://orthopundit.com/2018/05/>)
- › April 2018 (<https://orthopundit.com/2018/04/>)
- › March 2018 (<https://orthopundit.com/2018/03/>)
- › February 2018 (<https://orthopundit.com/2018/02/>)
- › January 2018 (<https://orthopundit.com/2018/01/>)
- › December 2017 (<https://orthopundit.com/2017/12/>)
- › November 2017 (<https://orthopundit.com/2017/11/>)
- › October 2017 (<https://orthopundit.com/2017/10/>)
- › September 2017 (<https://orthopundit.com/2017/09/>)
- › August 2017 (<https://orthopundit.com/2017/08/>)
- › July 2017 (<https://orthopundit.com/2017/07/>)
- › June 2017 (<https://orthopundit.com/2017/06/>)
- › May 2017 (<https://orthopundit.com/2017/05/>)

- › April 2017 (<https://orthopundit.com/2017/04/>)
- › March 2017 (<https://orthopundit.com/2017/03/>)
- › February 2017 (<https://orthopundit.com/2017/02/>)
- › January 2017 (<https://orthopundit.com/2017/01/>)
- › December 2016 (<https://orthopundit.com/2016/12/>)
- › November 2016 (<https://orthopundit.com/2016/11/>)
- › October 2016 (<https://orthopundit.com/2016/10/>)
- › September 2016 (<https://orthopundit.com/2016/09/>)
- › August 2016 (<https://orthopundit.com/2016/08/>)
- › July 2016 (<https://orthopundit.com/2016/07/>)
- › June 2016 (<https://orthopundit.com/2016/06/>)
- › May 2016 (<https://orthopundit.com/2016/05/>)
- › April 2016 (<https://orthopundit.com/2016/04/>)
- › March 2016 (<https://orthopundit.com/2016/03/>)
- › February 2016 (<https://orthopundit.com/2016/02/>)
- › January 2016 (<https://orthopundit.com/2016/01/>)
- › December 2015 (<https://orthopundit.com/2015/12/>)
- › November 2015 (<https://orthopundit.com/2015/11/>)
- › October 2015 (<https://orthopundit.com/2015/10/>)
- › September 2015 (<https://orthopundit.com/2015/09/>)
- › August 2015 (<https://orthopundit.com/2015/08/>)
- › July 2015 (<https://orthopundit.com/2015/07/>)
- › June 2015 (<https://orthopundit.com/2015/06/>)
- › May 2015 (<https://orthopundit.com/2015/05/>)
- › April 2015 (<https://orthopundit.com/2015/04/>)

## Categories

- › Answer Dentist (<https://orthopundit.com/category/answer-dentist/>)
- › Clinical (<https://orthopundit.com/category/clinical/>)
- › Guest Contributors (<https://orthopundit.com/category/guest-contributors/>)
- › Happy Independant Kids (<https://orthopundit.com/category/happy-independant-kids/>)

- › Legal & HR (<https://orthopundit.com/category/legal-hr/>)
- › Leisure (<https://orthopundit.com/category/leisure/>)
- › Mindset (<https://orthopundit.com/category/mindset/>)
- › New Patient Process (<https://orthopundit.com/category/new-patient-process/>)
- › Orthodontic Marketing (<https://orthopundit.com/category/orthodontic-marketing/>)
- › Orthodontic Practice Growth & Development (<https://orthopundit.com/category/orthodontic-practice-growth-development/>)
- › OrthoPundit (<https://orthopundit.com/category/orthopundit/>)
- › Resident & Young Doc (<https://orthopundit.com/category/resident-young-doc/>)
- › Scripting (<https://orthopundit.com/category/scripting/>)
- › The State of Orthodontics (<https://orthopundit.com/category/the-state-of-orthodontics/>)
- › Uncategorized (<https://orthopundit.com/category/uncategorized/>)

## Meta

- › Log in (<https://orthopundit.com/wp-login.php>)
- › Entries feed (<https://orthopundit.com/feed/>)
- › Comments feed (<https://orthopundit.com/comments/feed/>)
- › WordPress.org (<https://wordpress.org/>)

Designed by [InkHive.com](http://inkhive.com.com/) (<http://inkhive.com.com/>).

# Exhibit 10

## FEDERAL COURT OF AUSTRALIA

### Australian Competition and Consumer Commission v SmileDirectClub LLC

[2022] FCA 1343

File number: VID 375 of 2021

Judgment of: **ANDERSON J**

Date of judgment: 11 November 2022

Catchwords: **CONSUMER PROTECTION** – misleading or deceptive conduct – where the Respondents engaged in misleading or deceptive conduct by making false representations in respect of consumers’ eligibility for reimbursement from private health insurers for Aligners and Aligner Treatment – where declaratory relief, pecuniary penalties, consumer redress orders, corrective communications and a compliance program will be ordered

Legislation: *Competition and Consumer Act 2010* (Cth)  
*Evidence Act 1995* (Cth)  
*Federal Court of Australia Act 1976* (Cth)

Cases cited: *ACCC v Cement Australia Pty Ltd* (2017) 258 FCR 312  
*ACCC v Clinica Internationale Pty Ltd (No 2)* [2016] FCA 62  
*ACCC v Coles Supermarkets Australia Pty Ltd* (2015) 327 ALR 540  
*ACCC v EnergyAustralia Pty Ltd* [2014] ATPR ¶42-469  
*ACCC v Geowash Pty Ltd (Subject to a Deed of Company Arrangement) (No 4)* (2020) 376 ALR 701  
*ACCC v Jetstar Airways Pty Ltd (No 2)* [2017] FCA 205  
*ACCC v Oscar Wylee Pty Ltd* [2020] FCA 1340  
*ACCC v Reckitt Benckiser (Australia) Pty Ltd* (2016) 340 ALR 25  
*ACCC v Safeway Stores Pty Ltd* (1997) 75 FCR 238; (1997) 145 ALR 36  
*ACCC v Sontax Australia* (1988) Pty Ltd [2011] ATPR ¶42-379  
*ACCC v TPG Internet Pty Ltd* (2013) 250 CLR 640  
*ACCC v Woolworths Limited* [2016] FCA 44  
*ACCC v Yazaki Corporation* (2018) 262 FCR 243  
*Ainsworth v Criminal Justice Commission* (1992) 175 CLR 564  
*ASIC v Axis International Management Pty Ltd* (2009) 178 FCR 485



*Australian Building and Construction Commissioner v Pattinson* [2022] HCA 13; (2022) 96 ALJR 426  
*Australian Softwood Forests Pty Ltd v Attorney-General (NSW)* (1981) 148 CLR 121  
*Commonwealth v Director, Fair Work Building Industry Inspectorate* (2015) 258 CLR 482  
*Construction, Forestry, Mining and Energy Union v Cahill* (2010) 269 ALR 1  
*Forster v Jododex Australia Pty Ltd* (1972) 127 CLR 421  
*Markarian v The Queen* (2005) 228 CLR 357  
*Minister for Industry, Tourism and Resources v Mobil Oil Australia Pty Ltd* (2004) ATPR ¶41,993  
*NW Frozen Foods Pty Ltd v ACCC* (1996) 71 FCR 285  
*Rural Press Limited v ACCC* (2003) 216 CLR 53  
*Singtel Optus Pty Ltd v ACCC* (2012) 287 ALR 249  
*Thomson Australian Holdings Pty Ltd v TPC* (1981) 148 CLR 150  
*Trade Practices Commission v CSR Ltd* (1991) ATPR ¶41-076  
*Trade Practices Commission v TNT Australia Pty Ltd* (1995) ATPR ¶41-375  
*Volkswagen Aktiengesellschaft v ACCC* (2021) 284 FCR 24

Division:	General Division
Registry:	Victoria
National Practice Area:	Commercial and Corporations
Sub-area:	Regulator and Consumer Protection
Number of paragraphs:	112
Date of hearing:	18 August 2022
Counsel for the Applicant:	Ms N Sharp SC with Ms C Cunliffe
Solicitor for the Applicant:	Johnson Winter & Slattery
Counsel for the Respondent:	Mr N De Young KC with Ms T Meyrick
Solicitor for the Respondent:	DLA Piper

**Table of Corrections**

6 December 2022	In Order 10, “5 years” has been replaced with “3 years”
6 December 2022	In Order 11(b), “5 years” has been replaced with “3 years”
6 December 2022	In subparagraph 14(d) of Annexure C to the Orders, “4 further years” has been replaced with “2 further years”
6 December 2022	In subparagraph 19 of Annexure C to the Orders, “7 years” has been replaced with “5 years”
6 December 2022	In paragraph 106, “ five years” has been replaced with “three years”

## ORDERS

VID 375 of 2021

**BETWEEN:**            **AUSTRALIAN COMPETITION AND CONSUMER  
COMMISSION**  
Applicant

**AND:**                **SMILEDIRECTCLUB LLC**  
First Respondent

**SMILEDIRECTCLUB AUS PTY LTD**  
Second Respondent

**ORDER MADE BY: ANDERSON J**

**DATE OF ORDER: 11 NOVEMBER 2022**

### THE COURT DECLARES THAT:

1. Between approximately 24 May 2019 and 8 October 2020, the First Respondent, SmileDirectClub LLC (**SDC LLC**), and Second Respondent, SmileDirectClub Aus Pty Ltd (**SDC AU**) (together, **SDC**), in trade or commerce:
  - (a) engaged in conduct that was misleading or deceptive, or likely to mislead or deceive, in contravention of section 18 of the Australian Consumer Law, being Schedule 2 of the *Competition and Consumer Act 2010* (Cth) (**ACL**);
  - (b) made false or misleading representations that goods or services had approval or benefits in contravention of section 29(1)(g) of the ACL; and
  - (c) made false or misleading representations concerning the existence, exclusion or effect of a condition or right in contravention of section 29(1)(m) of the ACL,by publishing, or causing to be published, statements on the website at [www.smiledirectclub.com.au/en-au](http://www.smiledirectclub.com.au/en-au) (**Website**) which contained representations:
  - (a) throughout that period, that some Australian private health insurers provide insurance cover for plastic teeth aligners promoted and supplied by SDC (**SDC Aligners**) and/or associated treatment (**Aligner Treatment**) (**Coverage Representation**);
  - (b) throughout that period, that after purchasing SDC Aligners, consumers may be eligible under their private health insurance for reimbursement of part of the cost of SDC Aligners and/or Aligner Treatment (**Future Eligibility Representation**);

- (c) during the period from about February 2020 to 8 October 2020, that consumers whose private health insurance covered items 811 and/or 825 are entitled to reimbursement from their private health insurers of part of the cost of SDC Aligners and/or Aligner Treatment (**Item 811/825 Representation**),

when that was false, misleading or deceptive, and further, in respect of the Future Eligibility Representation, when they did not have reasonable grounds for making that representation.

- 2. Between approximately 28 May 2019 and 1 October 2019, SDC AU, in trade or commerce:
  - (a) engaged in conduct that was misleading or deceptive, or likely to mislead or deceive, in contravention of section 18 of the ACL;
  - (b) made false or misleading representations that goods or services had approval or benefits in contravention of section 29(1)(g) of the ACL; and
  - (c) made false or misleading representations concerning the existence, exclusion or effect of a condition or right in contravention of section 29(1)(m) of the ACL,

by sending, or having sent on its behalf, emails to 648 consumers who had made enquiries with SDC about private health insurance coverage, and in addition text messages to 124 of those consumers, which contained:

- (a) the Coverage Representation;
- (b) the Future Eligibility Representation;
- (c) a representation that SDC AU had contacted the consumer's private health insurer to find out if that particular consumer's health insurance covered SDC Aligners and/or Aligner Treatment (**Individual Contact Representation**);
- (d) a representation that the particular consumer's health insurance covered SDC Aligners and/or Aligner Treatment (**Individual Cover Representation**),

when that was false, misleading or deceptive, and further, in respect of the Future Eligibility Representation, when they did not have reasonable grounds for making that representation.

- 3. In or about 2019, SDC AU, in trade or commerce:
  - (a) engaged in conduct that was misleading or deceptive, or likely to mislead or deceive, in contravention of section 18 of the ACL;
  - (b) made false or misleading representations that goods or services had approval or benefits in contravention of section 29(1)(g) of the ACL; and

- (c) made false or misleading representations concerning the existence, exclusion or effect of a condition or right in contravention of section 29(1)(m) of the ACL,

by sending, or having sent on its behalf, emails to consumers, other than those referred to in paragraph 2 above, who had made enquiries with SDC about private health insurance coverage which contained:

- (a) the Coverage Representation;
- (b) the Future Eligibility Representation;
- (c) the Item 811/825 Representation,

when that was false, misleading or deceptive, and further, in respect of the Future Eligibility Representation, when they did not have reasonable grounds for making that representation.

4. From 20 June 2019 to 20 December 2019, SDC AU, in trade or commerce:

- (a) engaged in conduct that was misleading or deceptive, or likely to mislead or deceive, in contravention of section 18 of the ACL;
- (b) made false or misleading representations that goods or services had approval or benefits in contravention of section 29(1)(g) of the ACL; and
- (c) made false or misleading representations concerning the existence, exclusion or effect of a condition or right in contravention of section 29(1)(m) of the ACL,

by distributing to consumers in its retail stores in Australia called SmileShops a printed card which contained:

- (a) the Coverage Representation;
- (b) the Future Eligibility Representation;
- (c) the Item 811/825 Representation,

when that was false, misleading or deceptive, and further, in respect of the Future Eligibility Representation, when they did not have reasonable grounds for making that representation.

**THE COURT ORDERS THAT:**

***Pecuniary penalties***

5. Pursuant to section 224(1) of the ACL, the Respondents pay to the Commonwealth of Australia pecuniary penalties in respect of the contraventions of sections 29(1)(g) and 29(1)(m) of the ACL referred to in paragraphs 1 to 4 above, as follows:

- (a) in respect of SDC LLC, pecuniary penalties in the amount of \$1.75 million; and

- (b) in respect of SDC AU, pecuniary penalties in the amount of \$1.75 million.
6. Each Respondent is to pay its pecuniary penalties referred to in paragraph 5 above in 6 equal instalments of \$291,666.67, payable as follows:
- (a) an instalment within 7 days of the date of this order;
  - (b) an instalment within 6 months of the date of this order;
  - (c) an instalment within 12 months of the date of this order;
  - (d) an instalment within 18 months of the date of this order;
  - (e) an instalment within 24 months of the date of this order; and
  - (f) an instalment within 30 months of the date of this order.
7. In the event that a Respondent is in default of any of the instalment payments referred to in paragraph 6 above by any more than 14 days, the whole of the outstanding amount of the pecuniary penalty specified in paragraph 5 above in respect of that Respondent is immediately due and payable by that Respondent.

***Consumer redress***

8. Pursuant to section 239 of the ACL, the Respondents provide redress to non-party consumers, in accordance with the methodology set out in Annexure A to this order:
- (a) to each customer set out in Column A;
  - (b) payment of the amount set out in Column B;
  - (c) subject to the conditions set out in Column C and under the heading “General conditions attaching to consumer redress” in Annexure A.

***Publication orders***

9. Pursuant to section 246(2)(d) of the ACL, the Respondents must jointly issue to each Australian consumer who purchased SDC Aligners and/or Aligner Treatment during the period 1 May 2019 and 31 October 2020 inclusive, a notice in the form set out in Annexure B to these orders at their own expense within 30 days of this order.

***Compliance orders***

10. Pursuant to section 246(2)(b) of the ACL, each of the Respondents, at their own expense, establish and implement an Australian Consumer Law Compliance Program in accordance with Annexure C, and maintain that program for a period of at least 3 years from the date of this order.



***Other orders***

11. The Respondents serve on the Applicant:
  - (a) an affidavit verifying that it has carried out its obligations under paragraph 9 above, to be served within 37 days of this order;
  - (b) an affidavit verifying that it has carried out its obligations under paragraph 8 above, and including:
    - (i) the number of consumers who made claims for redress;
    - (ii) the number of consumers granted redress and amounts paid; and
    - (iii) the reasons for rejection of any claims for redress,to be served within 9 months of this order;
  - (a) an affidavit verifying that it has carried out its obligations under paragraph 10 above as set out in paragraphs 1 to 8 of Annexure C, to be served within 4 months of this order;
  - (b) an affidavit verifying that it has carried out its obligations under paragraph 10 of this order, to be served within 3 years and 1 month of this order.
12. The Respondents are jointly and severally liable to pay a contribution to the Applicant's costs of, and incidental to, this proceeding in the fixed amount of \$100,000 within 7 days of the date of this order.

Note: Entry of orders is dealt with in Rule 39.32 of the *Federal Court Rules 2011*.

## ANNEXURE A

COLUMN A (CUSTOMER CATEGORY)	COLUMN B (REDRESS AMOUNT)	COLUMN C (CONDITIONS)
<p><i>Category 1 – Recipients of Good News communications</i></p> <p>All customers who were sent the Good News Email, who have not already received a refund from SDC and who purchased SDC’s aligners and/or associated treatment in the period 1 May 2019 to 31 October 2020.</p>	<p>SDC will pay to the customer:</p> <p>a. If the customer was also sent a Good News Text, a refund of:</p> <p>i. \$925 (being the amount of potential reimbursement savings to which SDC represented the customer may be entitled in the Good News Text); or</p> <p>ii. the amount SDC understands was referred to in the Good News Email sent to that particular customer; or</p> <p>iii. where the amount referred to in the Good News Email sent to that particular customer cannot be ascertained, \$1,174.24,</p> <p>whichever is the higher; and</p> <p>b. For all other customers who were sent the Good News Email, and in respect of each</p>	<p>The customer must provide to SDC a declaration (in a form to be provided by SDC to the customer) that they:</p> <p>a. either made a claim for an insurance payment in respect of SDC’s aligners and/or associated treatment, or made enquiries about their insurance coverage after the purchase of the aligners and found that such a claim would not be allowed (or, for customers who commenced treatment in the period 1 May 2019 and 31 October 2020 but who are still completing their instalment plan, they intended to make such a claim before or at the completion of their plan); and</p> <p>b. either have not received an insurance payment in respect of SDC’s aligners and/or associated treatment or have received an insurance payment in an amount specified in that declaration (which is less than the amount of the refund from SDC to which they would otherwise be entitled); and</p> <p>c. will not in the future seek an insurance payment or any further insurance payment (as the case may be) in respect of their purchase between 1 May 2019 and 31 October 2020 of SDC’s aligners and/or associated treatment.</p>

	such customer, a refund in the amount SDC understands was referred to in the email sent to that customer or, where that amount cannot be ascertained, a refund in the amount of \$1,174.24.	
<p><i>Category 2 – All other SDC customers in the period 1 May 2019 to 31 October 2020</i></p> <p>All other customers who received SDC's aligners and/or associated treatment in the period from 1 May 2019 to 31 October 2020.</p>	<p>SDC will pay to the customer:</p> <ol style="list-style-type: none"> <li>A refund in an amount equivalent to the reimbursement they would have been entitled to from their private health insurer had their orthodontic coverage entitled them to a reimbursement for SDC's aligners and/or associated treatment; or</li> <li>otherwise, a refund in the amount of \$1,174.24.</li> </ol>	<p>The customer must provide to SDC:</p> <ol style="list-style-type: none"> <li>a copy of a document from their private health insurer that evidences that they had private health insurance at the relevant time which included extras coverage for orthodontic treatment;</li> <li>a statutory declaration (in a form to be provided by SDC to the customer) that: <ol style="list-style-type: none"> <li>they either made a claim for an insurance payment in respect of SDC's aligners and/or associated treatment or made enquiries about their insurance coverage after the purchase of the aligners and found that such a claim would not be allowed (or, for customers who commenced treatment in the period 1 May 2019 to 31 October 2020 but who are still completing their instalment plan, they intended to make such a claim before or at the completion of their plan);</li> <li>they either have not received an insurance payment in respect of SDC's aligners and/or associated</li> </ol> </li> </ol>

		<p>treatment or have received an insurance payment in an amount specified in that declaration; and</p> <p>iii. they will not in the future seek an insurance payment or any further insurance payment (as the case may be) in respect of their purchase between 1 May 2019 and 31 October 2020 of SDC's aligners and/or associated treatment; and</p> <p>c. if the customer seeks a refund in an amount equivalent to the reimbursement they would have been entitled to from their private health insurer had their orthodontic coverage entitled them to a reimbursement for SDC's aligners and/or associated treatment, evidence of the amount of the reimbursement they would have been entitled to from their private health insurer had their orthodontic coverage entitled them to a reimbursement for SDC's aligners and/or associated treatment.</p>
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#### **GENERAL CONDITIONS ATTACHING TO CONSUMER REDRESS**

1. SDC's offer of a refund to the customers in categories 1 and 2 above will be open for 90 days from the date the offer is made.
2. In each case:

- a. where the customer has received any insurance payment/s from their private health insurer in respect of SDC's aligners and/or associated treatment, SDC will refund them the amount to which they are entitled as set out in Column B less the payment/s the customer has received from their insurer;
- b. where the customer has received a refund from SDC in respect of non-reimbursement from an insurer which is less than the amount to which they are entitled as set out in Column B, SDC will refund them the amount to which they are entitled less the refund payment the customer previously received from SDC;
- c. the amount of the refund payable by SDC will be capped at the total cost incurred by the customer for SDC's aligners and/or associated treatment less any refunds previously received by that customer (received from SDC for any reason). For the avoidance of doubt, any refund shall not affect any customer's entitlement to or payment for compensation for personal injury or otherwise;
- d. SDC will make the refund payment within 45 days of receipt of a claim with the required supporting information; and
- e. customers who commenced treatment in the period 1 May 2019 and 31 October 2020 but who are still completing their instalment plan may nonetheless make a claim. That is, these customers may make a claim for compensation from SDC without having to wait until the end of their instalment plan. Payment of the refund amount will then be made by SDC by deducting the refund amount from the remaining payments due under the customer's instalment plan (and, if the refund due is greater than the amount still owing, making a refund for the difference).

**ANNEXURE B**

*[The notice to be provided by SDC to those customers identified in Column A of Annexure A as category 1 customers]*

[SDC letter head]

By email – [Insert email address]

[date]

Dear [Customer name]

**Refund from SmileDirectClub following ACCC action**

You are receiving this letter because you may be eligible for a refund from SmileDirectClub following a recent court action brought by the Australian Competition and Consumer Commission (ACCC). The refunds are being offered to certain eligible customers who purchased SmileDirectClub plastic teeth aligners and/or associated treatment between 1 May 2019 and 31 October 2020 (**Aligner Treatment**).

Depending on your particular circumstances, a refund of up to a maximum amount of \$[insert amount] may be available to you. If you are not sure whether you are eligible, we encourage you to submit a claim and we will check your eligibility.

**STEPS TO CHECK YOUR ELIGIBILITY AND CLAIM A REFUND**

<input type="checkbox"/>	Check if you are eligible – see <b><u>paragraphs 1-3</u></b> of this letter
<input type="checkbox"/>	Complete the Declaration attached to this letter if you are eligible (or if you are unsure of your eligibility)
<input type="checkbox"/>	Submit your claim (with the completed Declaration) by emailing us at <a href="mailto:refunds@smiledirectclub.com.au">refunds@smiledirectclub.com.au</a> by no later than <b>[date 90 days from the date of this letter in bold]</b>
<input type="checkbox"/>	Let us know if your payment details have changed (optional)



## Background

The Federal Court of Australia has ordered SmileDirectClub to implement a customer refund program upon finding, based on joint submissions by the parties, that, from 24 May 2019 to 8 October 2020, SmileDirectClub misled Australian consumers about the potential for private health insurance cover for the Aligner Treatment. You have been sent this letter in accordance with this refund program.

More information on the action taken by the ACCC is available on the ACCC's website at [media release URL to specific ACCC announcement regarding Federal Court decision in this matter].

### Are you eligible for a refund from SmileDirectClub?

We have identified you as a customer who may be eligible for a refund. This is because you:

- were sent an email with the subject 'Good News about your private health fund' in response to your enquiries with SmileDirectClub about private health insurance coverage, which contained representations about your eligibility for that coverage (**Good News Email**); and
- purchased the Aligner Treatment.

You may have also received an SMS text message from us which said 'Good news [name], we've contacted your private health fund provider and it looks like with your Orthodontia coverage that you are eligible for up to \$925 in potential reimbursement savings' (**Good News Text**).

To be eligible for a refund you must:

1. Have either:
  - a. made a claim for private health insurance reimbursement in respect of the Aligner Treatment; or
  - b. made enquiries about your private health insurance coverage after the purchase of the Aligner Treatment and found that such a claim would not be allowed; or
  - c. if you are completing your instalment plan, purchased the Aligner Treatment with the intention of making a claim for a private health insurance reimbursement in respect of that treatment; and

2. Have either:

- a. not received a private health insurance reimbursement in respect of the Aligner Treatment; or
- b. received a private health insurance reimbursement less than the refund you would be entitled to under this refund program; and

3. Confirm that you will not seek any future or further reimbursement/s from either your private health insurer or SmileDirectClub in relation to insurance coverage for the Aligner Treatment.

### **Claiming your refund**

To apply for a refund, you must complete and sign the declaration attached to this letter confirming that you meet the above requirements, and provide that signed declaration to us at [refunds@smiledirectclub.com.au](mailto:refunds@smiledirectclub.com.au) by no later than **[date 90 days from the date of this letter in bold]**.

### **How much is the refund?**

If you satisfy the above conditions, we will refund you up to a maximum of \$*[amount to be specified, which will be as follows:*

- *where the amount referred to in the Good News Email sent to the consumer can be ascertained by SmileDirectClub, the greater of:*
  - *the amount SmileDirectClub understands was referred to in the Good News Email sent to the consumer; or*
  - *if the consumer also received a Good News Text, \$925 (being the amount of potential reimbursement savings it referred to); or*
- *where the amount referred to in the Good News Email sent to the consumer cannot be ascertained by SmileDirectClub, a default refund amount of \$1,174.24.]*

This maximum refund amount may be adjusted as follows:

- If you have received any insurance reimbursement from your private health insurer for the Aligner Treatment, your refund will be reduced by the total amount of the reimbursement(s);

- If you have previously received a refund from SmileDirectClub because of non-reimbursement from your private health insurer, your refund will be reduced by the amount of that previous refund; and/or
- Your refund will be capped at the amount you paid for the Aligner Treatment, less any refunds you have previously received from SmileDirectClub for any reason.

**When and how will you receive any refund you are entitled to?**

We will pay your refund within 45 days of receipt of your completed and signed declaration.

If you have paid in full for the Aligner Treatment, we will pay the refund to your payment method as previously provided to us.

If you are completing an instalment plan for the Aligner Treatment, you may claim a refund from us now. The refund will be credited against the remaining payments due under your instalment plan. If the refund is more than the payments remaining, we will pay the difference to your payment method previously provided to us.

If, following receipt of your complete claim (with the completed declaration), we determine you are not eligible for a refund, we will reply to you within 45 days to inform you of that determination and the reasons for that determination.

Please let us know if your payment method is no longer current.

**Have you got questions?**

If you have any queries or concerns regarding your eligibility for a refund, how to demonstrate your eligibility, or the payment of your refund, please contact us at [refunds@smiledirectclub.com.au](mailto:refunds@smiledirectclub.com.au) or +61 (02) 6145 2903.

[Insert sign off for SDC US and SDC AU]

**SmileDirectClub Customer Refund Program**

**DECLARATION**

My name is.....

My address is.....

My occupation is.....

I make the following declaration:

1. I [*\*please select the box applicable to you*]:

☐ made a claim for a private health insurance reimbursement in respect of SmileDirectClub plastic teeth aligners and/or associated treatment that I purchased in the period from 1 May 2019 to 31 October 2020; **OR**

☐ made enquiries about my private health insurance coverage after I purchased SmileDirectClub plastic teeth aligners and/or associated treatment in the period from 1 May 2019 to 31 October 2020 and found that a claim would not be allowed; **OR**

☐ am completing my instalment plan for payment for SmileDirectClub plastic teeth aligners and/or associated treatment that I purchased in the period from 1 May 2019 to 31 October 2020, and at the time of making that purchase I intended to make a claim for a private health insurance reimbursement for those aligners and/or associated treatment.

2. I have [*\*please select the box applicable to you*]:

☐ not received any reimbursement from my private health insurer for the SmileDirectClub plastic teeth aligners and/or associated treatment referred to in paragraph 1 above; **OR**

☐ received reimbursement(s) from my private health insurer for the SmileDirectClub plastic teeth aligners and/or associated treatment referred to in paragraph 1 above totalling \$.....[*insert*].

*[If you select the second option, please insert the total amount of reimbursement you have received from your insurer for the treatment specified in paragraph 1 above]*

3. If I receive a refund from SmileDirectClub under this refund program, I will not seek any future or further reimbursement from either my insurer or SmileDirectClub in respect of insurance cover for the SmileDirectClub plastic teeth aligners and/or associated treatment referred to in paragraph 1 above.

.....  
*[Signature of person making the declaration]*

Declared at .....**[place]** on .....**[day]** of .....**[month]** 2022

***[The following notice to be provided by SDC by email 2 weeks before the scheme closes to those customers identified in Column A of Annexure A as category 1 customers who have not applied for a refund as at that date]***

Subject: SmileDirectClub refund: Reminder to take action now

Dear [name],

The SmileDirectClub refund scheme is closing on [date].

We previously wrote to you on [date] because you may be eligible for a refund following court action against SmileDirectClub by the Australian Competition and Consumer Commission (ACCC).

Depending on your personal circumstances, a refund of up to a maximum of \$[insert per letter] may be available.

You can check your eligibility by reading the information we sent to you via email on [date].

If you have any queries or concerns regarding your eligibility for a refund, how to demonstrate your eligibility, or the payment of your refund, please contact us at [refunds@smiledirectclub.com.au](mailto:refunds@smiledirectclub.com.au) or +61 (02) 6145 2903.

If you have already applied for a refund in response to our previous correspondence, please disregard this email. ***[This last sentence can be removed if the notice is sent only to consumers who haven't already applied for a refund under the redress program]***

[sign off for SDC US and SDC AU]



*[The notice to be provided by SDC to those customers identified in Column A of Annexure A as category 2 customers]*

[SDC letter head]

By email – [Insert email address]

[date]

Dear [Customer name]

### **Refund from SmileDirectClub following ACCC action**

You are receiving this letter because you may be eligible for a refund from SmileDirectClub following a recent court action brought by the Australian Competition and Consumer Commission (ACCC). The refunds are being offered to certain eligible customers who purchased SmileDirectClub plastic teeth aligners and/or associated treatment between 1 May 2019 and 31 October 2020 (**Aligner Treatment**).

Depending on your particular circumstances, a refund of up to \$1,174.24 (or more in some circumstances) may be available to you. If you are not sure whether you are eligible, we encourage you to submit a claim and we will check your eligibility.

### **STEPS TO CHECK YOUR ELIGIBILITY AND CLAIM A REFUND**

<input type="checkbox"/>	Check if you are eligible – see <b><u>paragraphs 1-4</u></b> of this letter
<input type="checkbox"/>	Obtain proof from your private health insurer that you had extras coverage for orthodontic treatment at the time of your purchase of the Aligner Treatment
<input type="checkbox"/>	Complete the Statutory Declaration attached to this letter
<input type="checkbox"/>	Sign your Statutory Declaration in front of an authorised witness
<input type="checkbox"/>	Submit your claim (including supporting evidence) by emailing us at <a href="mailto:refunds@smiledirectclub.com.au">refunds@smiledirectclub.com.au</a> by <b>[date 90 days from the date of this letter in bold]</b>
<input type="checkbox"/>	Let us know if your payment details have changed (optional)

## **Background**

The Federal Court of Australia has ordered SmileDirectClub to implement a customer refund program upon finding, based on joint submissions by the parties, that, from 24 May 2019 to 8 October 2020, SmileDirectClub misled Australian consumers about the potential for private health insurance cover for the Aligner Treatment. You have been sent this letter in accordance with this refund program.

More information on the action taken by the ACCC is available on the ACCC's website at [media release URL to specific ACCC announcement regarding Federal Court decision in this matter].

## **Are you eligible for a refund from SmileDirectClub?**

We have identified you as a customer who may be eligible for a refund. This is because you purchased the Aligner Treatment.

To be eligible for a refund you must:

1. Have had private health insurance which applied at the time of your purchase of the Aligner Treatment and which included extras coverage for orthodontic treatment; and
2. Have either:
  - a. made a private health insurance claim for a reimbursement in respect of the Aligner Treatment; or
  - b. made enquiries about your private health insurance coverage after the purchase of the Aligner Treatment and found that such a claim would not be allowed; or
  - c. if you are completing your instalment plan, purchased the Aligner Treatment with the intention of making a claim for a private health insurance reimbursement for that treatment; and
3. Have either:
  - a. not received a private health insurance reimbursement in respect of the Aligner Treatment; or

- b. received a private health insurance reimbursement less than the refund you would be entitled to under this refund program; and
4. Confirm that you will not seek any future or further reimbursement from either your private health insurer or SmileDirectClub in relation to insurance coverage for the Aligner Treatment.

### **Claiming your refund**

To apply for a refund, you must provide to us at [refunds@smiledirectclub.com.au](mailto:refunds@smiledirectclub.com.au) by no later than **[date 90 days from the date of this letter in bold]**:

- a. A copy of a document from your private health insurer that shows you had private health insurance which applied at the time of your purchase of the Aligner Treatment and which included extras coverage for orthodontic treatment.
- b. A statutory declaration as attached to this letter which confirms that you meet the requirements at 2 to 4 above. In the attached statutory declaration, you must select the statements that apply to you, and then take the document to an authorised witness and sign it in their presence. A list of authorised witnesses is at the back of the attached declaration. Please note it is an offence to make a false statutory declaration.

### **How much is the refund?**

If you satisfy the above conditions, we will refund you an amount up to the greater of:

- **\$1,174.24**; or
- an amount equivalent to the reimbursement you would have been entitled to from your private health insurer had your orthodontic coverage actually entitled you to a reimbursement for the Aligner Treatment.

If you wish to receive a refund based on the amount of the reimbursement you would have been entitled to from your private health insurer had your orthodontic coverage actually entitled you to a reimbursement for the Aligner Treatment, you will need to provide evidence of that amount, for example with reference to a private health insurance policy, or schedule, or written confirmation from your insurer. This is in addition to the document from your private health

insurer that shows that you had private health insurance which applied at the time of your purchase of the Aligner Treatment and which included extras coverage for orthodontic treatment and a statutory declaration of the kind described above.

The above refund amount may be adjusted as follows:

- If you have received any insurance reimbursement from your private health insurer for your purchase of the Aligner Treatment, your refund will be reduced by the total amount of the reimbursement(s);
- If you have previously received a refund from us because of non-reimbursement from your private health insurer, your refund will be reduced by the amount of that previous refund; and/or
- Your refund will be capped at the total amount you paid for the Aligner Treatment, less any refunds you have previously received from SmileDirectClub for any reason.

**When and how will you receive any refund you are entitled to?**

We will pay your refund within 45 days of receipt of the following documents:

- a. a completed statutory declaration; and
- b. the document from your private health insurer that shows you had private health insurance which applied at the time of your purchase of the Aligner Treatment and which included extras coverage for orthodontic treatment; and
- c. if (instead of a refund based on the default refund amount of \$1,174.24) you seek a refund based on the amount of the reimbursement you would have been entitled to from your private health insurer had your orthodontic coverage actually entitled you to a reimbursement for the Aligner Treatment, evidence of that amount.

If you have paid in full for the Aligner Treatment, we will pay the refund to your payment method as previously provided to us.

If you are completing an instalment plan for the Aligner Treatment, you may claim a refund from us now. The refund will be credited against the remaining payments due under your instalment plan. If the refund is more than the payments remaining, we will pay the difference to your payment method previously provided to us.

If, following receipt of your complete claim (with the supporting evidence), we determine you are not eligible for a refund, we will reply to you within 45 days to inform you of that determination and the reasons for that determination.

Please let us know if your payment method is no longer current.

**Have you got questions?**

If you have any queries or concerns regarding your eligibility for a refund, how to demonstrate your eligibility, or the payment of your refund, please contact us at [refunds@smiledirectclub.com.au](mailto:refunds@smiledirectclub.com.au) or +61 (02) 6145 2903.

[Insert sign off for SDC US and SDC AU]

**SmileDirectClub Customer Refund Program**

**STATUTORY DECLARATION**

*Statutory Declarations Act 1959*

I, .....

[Insert name]

of .....,

[insert address]

.....,

[insert occupation or alternatively, unemployed or retired]

make the following statutory declaration under the *Statutory Declarations Act 1959* (Cth):

1. I [*\*please select the box applicable to you*]:

☐ made a claim for a private health insurance reimbursement in respect of SmileDirectClub plastic teeth aligners and/or associated treatment that I purchased in the period from 1 May 2019 to 31 October 2020; **OR**

☐ made enquiries about my private health insurance coverage after I purchased SmileDirectClub plastic teeth aligners and/or associated treatment in the period from 1 May 2019 to 31 October 2020 and found that a claim would not be allowed; **OR**

☐ am completing my instalment plan for SmileDirectClub plastic teeth aligners and/or associated treatment that I purchased in the period from 1 May 2019 to 31 October 2020, and at the time of making that purchase I intended to make a claim for a private health insurance reimbursement in respect of those aligners and/or associated treatment.

2. I have [*\*please tick the box applicable to you*]:



☐ not received any reimbursement from my private health insurer in respect of the SmileDirectClub plastic teeth aligners and/or associated treatment referred to in paragraph 1 above; **OR**

☐ received a reimbursement or reimbursements from my private health insurer in respect of the SmileDirectClub plastic teeth aligners and/or associated treatment referred to in paragraph 1 above totalling \$.....[insert].

*[If you select the second option, please insert the total amount of reimbursements you have received from your insurer for the treatment referred to in paragraph 1 above.]*

3. If I receive a refund from SmileDirectClub under this refund program, I will not seek any future or further reimbursement from either my insurer or SmileDirectClub in respect of insurance cover for the SmileDirectClub plastic teeth aligners and/or associated treatment referred to in paragraph 1 above.

I understand that a person who intentionally makes a false statement in a statutory declaration is guilty of an offence under section 11 of the *Statutory Declarations Act 1959*, and I believe that the statements in this declaration are true in every particular.

.....  
[Signature of person making the declaration]

Declared at .....[*place*] on .....[*day*] of .....[*month*] 2022

Before me,

.....  
[Signature of person before whom the  
declaration is made]  
[Insert full name, qualification and address of  
person before whom the declaration is made (in  
printed letters)]

Note 1: A person who intentionally makes a false statement in a statutory declaration is guilty of an offence, the punishment for which is imprisonment for a term of 4 years—see section 11 of the *Statutory Declarations Act 1959*.

Note 2: Chapter 2 of the Criminal Code applies to all offences against the *Statutory Declarations Act 1959*—see section 5A of the *Statutory Declarations Act 1959*.

**A statutory declaration under the Statutory Declarations Act 1959 may be made before—**

(1) a person who is currently licensed or registered under a law to practise in one of the following occupations:

Architect	Chiropractor	Dentist
Financial adviser	Financial Planner	Legal practitioner
Medical practitioner	Midwife	Migration agent registered under Division 3 of Part 3 of the Migration Act 1958
Nurse	Occupational therapist	Optometrist
Patent attorney	Pharmacist	Physiotherapist
Psychologist	Trade marks attorney	Veterinary surgeon

(2) a person who is enrolled on the roll of the Supreme Court of a State or Territory, or the High Court of Australia, as a legal practitioner (however described); or

(3) a person who is in the following list:

- Accountant who is:
  - a) a fellow of the National Tax Accountants' Association; or
  - b) a member of any of the following:
    - i. Chartered Accountants Australia and New Zealand;
    - ii. the Association of Taxation and Management Accountants;
    - iii. CPA Australia;
    - iv. the Institute of Public Accountants
- Agent of the Australian Postal Corporation who is in charge of an office supplying postal services to the public
- APS employee engaged on an ongoing basis with 5 or more years of continuous service who is not specified in another item in this list
- Australian Consular Officer or Australian Diplomatic Officer (within the meaning of the Consular Fees Act 1955)
- Bailiff
- Bank officer with 5 or more continuous years of service
- Building society officer with 5 or more years of continuous service
- Chief executive officer of a Commonwealth court
- Clerk of a court

- Commissioner for Affidavits
- Commissioner for Declarations
- Credit union officer with 5 or more years of continuous service
- Employee of a Commonwealth authority engaged on a permanent basis with 5 or more years of continuous service who is not specified in another item in this list
- Employee of the Australian Trade and Investment Commission who is:
  - a) in a country or place outside Australia; and
  - b) authorised under paragraph 3 (d) of the Consular Fees Act 1955; and
  - c) exercising the employee's function at that place
- Employee of the Commonwealth who is:
  - a) at a place outside Australia; and
  - b) authorised under paragraph 3 (c) of the Consular Fees Act 1955; and
  - c) exercising the employee's function at that place
- Engineer who is:
  - a) a member of Engineers Australia, other than at the grade of student; or
  - b) a Registered Professional Engineer of Professionals Australia; or
  - c) registered as an engineer under a law of the Commonwealth, a State or Territory; or
  - d) registered on the National Engineering Register by Engineers Australia
- Finance company officer with 5 or more years of continuous service
- Holder of a statutory office not specified in another item in this list
- Judge
- Justice of the Peace
- Magistrate
- Marriage celebrant registered under Subdivision C of Division 1 of Part IV of the Marriage Act 1961
- Master of a court
- Member of the Australian Defence Force who is:
  - a) an officer
  - b) a non-commissioned officer within the meaning of the Defence Force Discipline Act 1982 with 5 or more years of continuous service
  - c) a warrant officer within the meaning of that Act
- Member of the Australasian Institute of Mining and Metallurgy
- Member of the Governance Institute of Australia Ltd
- Member of:
  - a) the Parliament of the Commonwealth

- b) the Parliament of a State
  - c) a Territory legislature
  - d) a local government authority
- Minister of religion registered under Subdivision A of Division 1 of Part IV of the Marriage Act 1961
- Notary public, including a notary public (however described) exercising functions at a place outside
  - a) the Commonwealth
  - b) the external Territories of the Commonwealth
- Permanent employee of the Australian Postal Corporation with 5 or more years of continuous service who is employed in an office providing postal services to the public
- Permanent employee of
  - a) a State or Territory or a State or Territory authority
  - b) a local government authority with 5 or more years of continuous service, other than such an employee who is specified in another item of this list
- Person before whom a statutory declaration may be made under the law of the State or Territory in which the declaration is made
- Police officer
- Registrar, or Deputy Registrar, of a court
- Senior executive employee of a Commonwealth authority
- Senior executive employee of a State or Territory
- SES employee of the Commonwealth
- Sheriff
- Sheriff's officer
- Teacher employed on a permanent full-time or part-time basis at a school or tertiary education institution

***[The following notice to be provided by SDC by email 2 weeks before the scheme closes to those customers identified in Column A of Annexure A as category 2 customers who have not applied for a refund as at that date]***

Subject: SmileDirectClub refund: Reminder to take action now

Dear [name],

The SmileDirectClub refund scheme is closing on [date].

We previously wrote to you on [date] because you may be eligible for a refund following court action against SmileDirectClub by the Australian Competition and Consumer Commission (ACCC).

Depending on your personal circumstances, a refund of up to \$1,174.24 (or more in some circumstances) may be available.

You can check your eligibility by reading the information we sent to you via email on [date].

If you have any queries or concerns regarding your eligibility for a refund, how to demonstrate your eligibility, or the payment of your refund, please contact us at [refunds@smiledirectclub.com.au](mailto:refunds@smiledirectclub.com.au) or +61 (02) 6145 2903.

If you have already applied for a refund in response to our previous correspondence, please disregard this email. ***[This last sentence can be removed if the notice is sent only to consumers who haven't already applied for a refund under the redress program]***

[sign off for SDC US and SDC AU]



## ANNEXURE C

### CONSUMER COMPLIANCE PROGRAM

SmileDirectClub will establish a Consumer Compliance Program (**Compliance Program**) that applies, where relevant, to SmileDirectClub Aus Pty Ltd, SmileDirectClub LLC and their related entities (collectively **SDC**) and complies with each of the following requirements:

#### APPOINTMENTS

1. Within 30 days of the order coming into effect, SDC will appoint a director or a senior manager with suitable qualifications or experience in corporate compliance as a Compliance Officer with responsibility for ensuring the Compliance Program is effectively designed, implemented and maintained (the **Compliance Officer**).
2. Within 60 days of the order coming into effect, SDC will appoint a suitably qualified internal or external, compliance professional or legal practitioner with expertise in the Australian Consumer Law (**ACL**) (contained in Schedule 2 of the Competition and Consumer Act 2010 (**CCA**)) (the **Compliance Advisor**).
3. Within 60 days of the order coming into effect, SDC will instruct the Compliance Advisor to conduct a consumer law risk assessment within 3 months of being appointed as the Compliance Advisor (the **Risk Assessment**).
4. SDC will use its best endeavours to ensure that the Risk Assessment covers the following matters, to be recorded in a written report (**Risk Assessment Report**):
  - a. identifies the areas where SDC is at risk of breaching sections 18 and 29 of the ACL;
  - b. assesses the likelihood of these risks occurring;
  - c. identifies where there may be gaps in SDC's existing procedures for managing these risks; and
  - d. provides recommendations for any action to be taken by SDC having regard to the above assessment.

#### COMPLIANCE OFFICER TRAINING

5. Within 3 months of the order coming into effect, SDC will ensure that the Compliance Officer attends practical training focusing on sections 18 and 29 of the ACL.
6. SDC will ensure that the training is administered by the Compliance Advisor.

#### COMPLIANCE POLICY

7. Within 3 months of the order coming into effect, SDC will issue an internal policy statement which will include an outline of SDC's commitment to compliance with the ACL (the **Compliance Policy**).

8. SDC will ensure that the Compliance Policy contains:
  - a. a statement of commitment to compliance with the ACL;
  - b. an outline of how SDC will promote compliance with the ACL;
  - c. a requirement for all staff to report any ACL compliance issues (including ACL compliance concerns) to the Compliance Officer;
  - d. a guarantee that whistle blowers with ACL compliance concerns will not be prosecuted or disadvantaged in any way and that their reports will be kept confidential and secure; and
  - e. a statement that SDC will take action internally against any person who is knowingly or recklessly concerned in a contravention of the ACL.

#### **STAFF TRAINING**

9. SDC will cause all employees of SDC whose duties could result in them being concerned with conduct that may contravene the ACL to receive regular (at least once a year) training administered by the Compliance Officer (once trained) or the Compliance Advisor, that focuses on sections 18 and 29 of the ACL.
10. SDC must ensure that the training is developed by a suitably qualified compliance professional or legal practitioner with expertise in the ACL.
11. SDC will take reasonable steps to ensure that the Compliance Program includes a requirement that awareness of sections 18 and 29 of the ACL forms part of the induction of all new directors, officers, employees, representatives and agents of SDC, whose duties include communicating with Australian consumers or dealing with their inquiries or complaints.

#### **COMPLAINTS HANDLING**

12. Within 6 months of the order coming into effect SDC will instruct the Compliance Advisor to conduct an assessment of whether SDC's complaints handling system (**Complaints Handling System**) is capable of identifying, classifying, storing and responding to consumer law complaints and, if not, make recommendations for actions to be taken by SDC.

#### **REPORTS TO DIRECTORS/GOVERNING BODY**

13. SDC will ensure that the Compliance Officer reports to SDC's director(s) or governing body every 12 months on the continuing effectiveness of the Compliance Program.

#### **COMPLIANCE REVIEW**

14. SDC will, at its own expense, cause an annual review of the Compliance Program (the Review) to be carried out in accordance with each of the following requirements:

- a. **Scope of Review** - the Review should be broad and rigorous enough to provide SDC and the ACCC with:
  - i. verification that SDC has in place a Compliance Program that complies with the requirements of the order and is suitable for the size and structure of SDC; and
  - ii. the Compliance Reports detailed at paragraph 15 below.
- b. **Independent Reviewer** - SDC will ensure that each Review is carried out by a suitably qualified, independent compliance professional with expertise in consumer law (the Reviewer). The Reviewer will qualify as independent on the basis that he or she:
  - i. did not design or implement the Compliance Program;
  - ii. is not a present or past staff member or director of SDC;
  - iii. has not acted and does not act for, and does not consult and has not consulted to, SDC in any consumer law related matters, other than performing Reviews under this order; and
  - iv. has no significant shareholding or other interests in SDC.
- c. **Evidence** - SDC will use its best endeavours to ensure that each Review is conducted on the basis that the Reviewer has access to all relevant sources of information in SDC's possession or control, including without limitation:
  - v. the ability to make enquiries of any officers, employees, representatives, and agents of SDC;
  - vi. documents relating to SDC's Compliance Program, including documents relevant to SDC's Complaints Handling System, Compliance Policy, Staff Training and induction program; and
  - vii. any reports made by the Compliance Officer to SDC director(s) or governing body regarding SDC's Compliance Program.
- d. SDC will ensure that a Review is completed within one year from the date of the order coming into effect and that a subsequent Review is completed within each year for 2 further years.

## COMPLIANCE REPORTS

15. SDC will use its best endeavours to ensure that within 30 days of the completion of a Review, the Reviewer includes the following findings of the Review in a report to the Compliance Officer (the **Compliance Report**):
  - a. whether the Compliance Program of SDC includes all the elements detailed in paragraphs 1 - 13 above, and if not, what elements need to be included or further developed;
  - b. whether the Compliance Program adequately covers the parties and areas identified in the Risk Assessment, and if not, what needs to be further addressed;
  - c. whether the Staff Training and induction is effective, and if not, what aspects need to be further developed;
  - d. whether SDC's Complaints Handling System is effective, and if not, what aspects need to be further developed; and
  - e. whether there are any material deficiencies in SDC's Compliance Program, or
  - f. whether there are or have been instances of material non-compliance with the Compliance Program (**Material Failure**)<sup>1</sup> and if so, recommendations for rectifying the Material Failure(s).

## SDC'S RESPONSE TO COMPLIANCE REPORTS

16. SDC will ensure that the Compliance Officer, within 14 days of receiving the Compliance Report:
  - a. provides the Compliance Report to the director(s) or governing body of SDC; and
  - b. where a Material Failure has been identified by the Reviewer in the Compliance Report, provides a report to SDC's director(s) or governing body identifying how SDC can implement any recommendations made by the Reviewer in the Compliance Report to rectify the Material Failure.
17. SDC will implement promptly and with due diligence any recommendations made by the Reviewer in the Compliance Report to address a Material Failure.

## **REPORTING MATERIAL FAILURES TO THE ACCC**

18. Where a Material Failure has been identified by the Reviewer in the Compliance Report, SDC will:
- a. provide a copy of the Compliance Report to the ACCC within 14 days of the Board or relevant governing body receiving the Compliance Report; and
  - b. inform the ACCC of any steps that have been taken to implement the recommendations made by the Reviewer in the Compliance Report; or
  - c. otherwise outline the steps SDC proposes to take to implement the recommendations and will then inform the ACCC once those steps have been implemented.

## **PROVISION OF COMPLIANCE PROGRAM DOCUMENTS TO THE ACCC**

19. SDC will maintain a record of and store all documents relating to and constituting the Compliance Program for a period of not less than 5 years from the date of the order coming into effect.
20. If requested by the ACCC during the period of 5 years from the date of the order coming into effect, SDC will, at its own expense, cause to be produced and provided to the ACCC, copies of all documents constituting the Compliance Program, including, but not limited to:
- a. the Compliance Policy;
  - b. the Risk Assessment report;
  - c. Staff Training materials and induction materials;
  - d. all Compliance Reports that have been completed at the time of the request; and
  - e. copies of the reports to the director(s) or governing body referred to in paragraphs 13 and 16.

## **ACCC RECOMMENDATIONS**

21. SDC will implement promptly and with due diligence any recommendations that the ACCC may make that the ACCC deems reasonably necessary to ensure that SDC maintains and continues to implement the Compliance Program in accordance with the requirements of this order.

# Exhibit 11

# SmileDirectClub: Moving Fast and Breaking Things in People's Mouths – 85% Downside

Published on October 4, 2019

GET OUR LATEST REPORTS DELIVERED TO YOUR INBOX

**SUBSCRIBE**

## Summary: SmileDirectClub (Nasdaq:SDC)

- SmileDirectClub is a company that claims to be disrupting orthodontics with its “teledentistry” platform and with its at-home ‘do it yourself’ model. We believe the company is carelessly cutting corners in a field of specialized medicine, putting customer safety at risk.
- Alabama and Georgia dental boards have enacted rules that render some of the company's practices illegal. We expect more states will follow suit.
- Major medical organizations like the American Dental Association and the American Association of Orthodontists have alleged that SmileDirectClub puts patients in danger and is practicing medicine illegally. They have filed complaints with the FTC, FDA, and at least 36 state boards.
- SmileDirectClub's practices have earned it over 1,200 Better Business Bureau complaints in just 5 years as a company. We communicated with one customer who was forced to use wire cutters to remove SDC products after he struggled to breathe. Review sites are replete with other horror stories of customers who had to take emergency dentistry into their own hands.
- While professional dentists offer personalized care and comprehensive pre-screening, we were told by a former SDC store manager that the company was sending 75 to 100 cases to one orthodontist's phone, per day, to “crank out” case decisions.
- Instead of fixing its practices, the company has gone on a litigation spree to silence critics. SDC has even required dissatisfied customers to sign legal releases promising not to complain to regulators or write bad online reviews, in exchange for refunds.
- The Chairman/CEO sold the company his private plane a month before the IPO – and *this wasn't even the first time* he sold the company an interest in one of his private planes. Insiders and affiliates cashed out almost \$700 million of \$1.27 billion in total net IPO proceeds.



- Financially, the company is another profitless, cash incinerating “unicorn” that we believe has significant added financial headwinds to face as a result of regulatory, legal and customer satisfaction liabilities.
- The company is trading at ~6.5x its revenue run-rate, an absurd multiple for a money-losing consumer products company with no meaningful barriers to entry. Well-funded, more responsible competitors are popping up left and right.
- All told, we believe SmileDirectClub will wind up as a case study in why it’s a bad idea to invest in a company that attempts to fit a complex, dangerous medical process onto a low-cost, high volume assembly line.
- We see downside of 70% purely on a valuation basis, and downside of 85% given the above headwinds. We have a one-year price target of \$2.

*Initial Disclosure: After extensive research, we have taken a short position in shares of SmileDirectClub. This report represents our opinion, and we encourage every reader to do their own due diligence. Please see our full disclaimer at the bottom of the report.*

## **Part I: SmileDirectClub is Another Ugly IPO That Has Somehow Avoided Even Basic Scrutiny**

In a year filled with busted and over-hyped Silicon Valley-backed IPOs, one company seems to have somehow slipped through the cracks largely unnoticed.

SmileDirectClub (“SDC” or “SmileDirect”) IPO’d on September 12<sup>th</sup> (<https://www.barrons.com/articles/smiledirectclub-ipo-first-trade-51568306975>), pricing its offering at a higher-than-expected \$23 a share, giving the young company an \$8.9 billion valuation (<https://www.cnbc.com/2019/09/11/smiledirectclub-prices-ipo-at-23-per-share-valuing-the-company-at-8point9-billion.html>). Since then, the stock has dropped over 40% and now trades at a ~\$5.2 billion valuation. From here, we expect the stock will be further cut in half several times over the next 6 to 12 months.

SmileDirectClub is a company that’s existence seems largely predicated on its ability to provide customers a lower-cost clear aligner treatment that meets the level of care of traditional orthodontics. Our investigation discovered evidence suggesting its level of care is not even close to the standard.

We believe that SmileDirectClub is putting customer safety at risk, potentially practicing medicine without proper licensing, and could end up as one of the worst consumer blowback stories in recent memory.

Once the market realizes the above, in conjunction with the company's financial and governance issues, we expect SmileDirectClub will reprice significantly lower and will be subject to long overdue scrutiny from investors, analysts and the press.

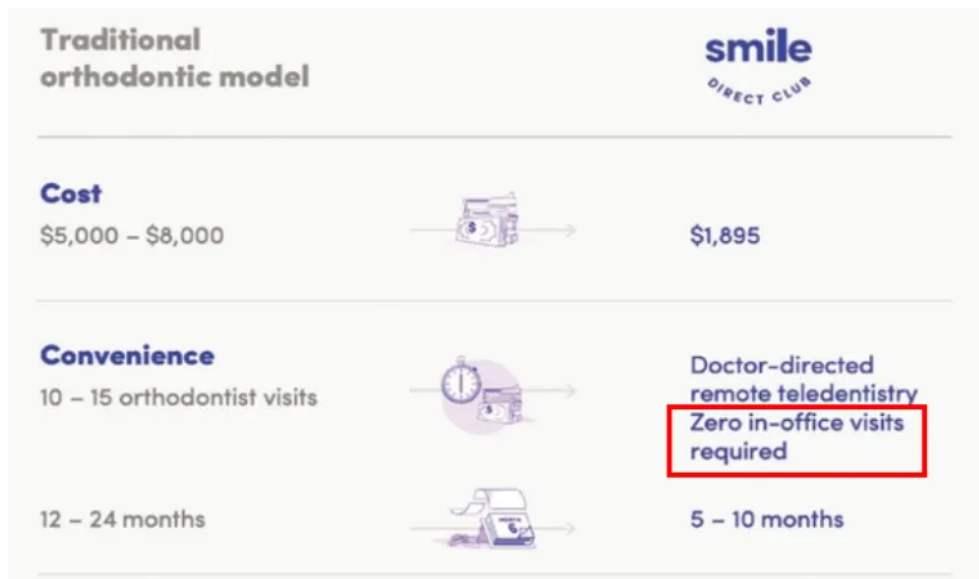
## About Our Investigation

During our investigation into SmileDirectClub, we spoke with multiple former employees, competitors, and customers. We reviewed the company's SEC filings and numerous court filings, visited one of the company's "Smile Shop" locations in New York City, and corresponded with dentists and orthodontists.

## Background: A Brief History of SmileDirectClub And Its Product

SmileDirectClub was founded in 2014 with a simple approach: offer inexpensive clear teeth aligners by cutting out expensive and time-consuming elements of the process.

The company's approach claims that it requires zero meetings with dentists or orthodontists, instead replacing them with a "teledentistry" platform.



(Source: Prospectus Pg. 1

(<https://www.sec.gov/Archives/edgar/data/1775625/000104746919005230/a2239665z424b4.htm>)

Users take their own dental impressions at home via a do-it-yourself kit or go to one of several hundred brick and mortar "Smile Shops" where their mouths are scanned by "Smile Guides".

Once approved, clear aligners are sent by mail to customers who then undergo 5-10 month treatment plans ([https://smiledirectclub.com/?&gclid=Cj0KCQjwuNbsBRC-ARIsAAzITuej95Wc\\_KXAXaC5etnFblwLQXzDkUkNru0ToFREWAx5OtPsLhQx3\\_waApowEALw\\_wcB&gclid=aw.ds](https://smiledirectclub.com/?&gclid=Cj0KCQjwuNbsBRC-ARIsAAzITuej95Wc_KXAXaC5etnFblwLQXzDkUkNru0ToFREWAx5OtPsLhQx3_waApowEALw_wcB&gclid=aw.ds)). The customers can communicate questions and issues through SmileDirect's customer service platform and the company's "Dental Team (<https://smiledirectclub.com/blog/doctors-behind-your-smile/>)" along the way.

SmileDirect was backed by some of Silicon Valley's most notable VCs, including Kleiner Perkins (<https://www.cdr-inc.com/news/press-release/smiledirectclub-announces-380-million-equity-private-placement-3.2-billion>). In just 5 short years, the company has gone from startup to multi-billion-dollar public company by employing its "disruptive" approach to specialized medicine.

## **Background: SmileDirect's Goal of "Disrupting" The Traditional Orthodontic Model Seems to Largely Rely on Dangerous Corner-Cutting**

We think SmileDirectClub is an ongoing case study in precisely why the best practices of the traditional dentistry model exist to begin with.

Throughout the course of our research, dentists and orthodontists were unanimous in telling us that SDC was missing the most vital parts of any orthodontic treatment, which include a comprehensive pre-screening and evaluation for complex legacy dental issues, professionally performed molds and/or scans, as well as continuing personalized care from a licensed professional.

During our research, we came across *"Do It Yourself" dental horror stories, allegations of practicing medicine without licenses, dental emergencies in the company's "Smile Shops" and lawsuits* – all of which we believe will help put the world – and the public markets – on notice about SDC's questionable approach.

## **Reality Check: State Regulators and Major Medical Organizations Have Begun to Declare the Company's Practices Illegal**

Several state dental boards have recently clamped down on SmileDirectClub with rules that render certain of the company's practices illegal. Major medical organizations have also come out swinging with complaints targeted directly at the company:

- **Alabama.** The Board of Dental Examiners of Alabama found that SmileDirect's practice of taking pictures of teeth for the purposes of creating dental products **constituted the**

**unlicensed practice of dentistry.** (Pg. 2

(<https://www.slideshare.net/secret/Dzq4rQJdNuAmzm>)) SmileDirect filed suit against the board, with most of its claims dismissed in April (<https://www.prnewswire.com/news-releases/federal-court-throws-out-six-of-smiledirectclubs-eleven-counts-against-the-alabama-dental-board-300834293.html>).

- **Georgia.** The Georgia Board of Dentistry clamped down on SmileDirect (<https://dentistrytoday.com/news/industrynews/item/4822-federal-court-finds-that-digital-scanning-constitutes-the-practice-of-dentistry>) with a rule that targeted the company's practice of allowing dental assistants to take digital scans of customer's mouths without any direct supervision from a licensed dentist. SmileDirect filed suit, but most of its claims were dismissed in May (<https://www.prnewswire.com/news-releases/federal-court-dismisses-a-majority-of-smiledirectclubs-claims-and-finds-that-smiledirectclubs-digital-scans-constitute-the-practice-of-dentistry-300850327.html>).
- **36 State Complaints** have been filed against ([https://www.aaoinfo.org/\\_/1-press-room/](https://www.aaoinfo.org/_/1-press-room/)) SmileDirect by state affiliates of the American Association of Orthodontists (AAO) alleging, in a substantiated fashion, that SmileDirect is illegally operating as a dentist without proper licensing in the subject states. See example here (<https://www.slideshare.net/secret/Maajh8OXtPEpZN>).
- **FDA** (<https://www.slideshare.net/secret/Fb6MHOigKskeic>) **and FTC** (<https://www.slideshare.net/secret/r5Wth2awFRTss4>) **Complaints have been filed by the American Dental Association** alleging that (<https://www.slideshare.net/secret/cMSW7zDYrbw1UA>) SmileDirect is "placing the public at risk" and alleging "false and misleading claims (that) constitute unfair and deceptive practices."

In response to the industry pushback, SmileDirect's CFO retorted in a recent Forbes interview (<https://www.forbes.com/sites/laurendebter/2019/09/11/smiledirectclub-ipo/#79d7401c6aca>) by saying:

*"I think anytime you do something disruptive, the status quo pushes back against that."*

– Kyle Wailes, SmileDirect's Chief Financial Officer

## **Reality Check: In Just Five Years as a Company, SDC Has Amassed 1,200 Better Business Bureau Complaints and a Damning New Class Action Lawsuit**

In addition to regulators, the company seems to be getting pushback from another important constituency—its customers. A review of the Better Business Bureau (BBB) website for SmileDirectClub shows over 1,200 customer complaints (<https://www.bbb.org/us/tn/nashville/profile/cosmetic-dentistry/smiledirectclub-0573-37111672/complaints>) as of this writing, **for a company that is only 5 years old!**

Just last week, a major lawsuit seeking class action status was filed (<https://www.slideshare.net/secret/cMSW7zDYrbw1UA>) against the company on behalf of customers and orthodontists/dentists.

Among its allegations, the lawsuit references “thousands of substantiated, serious customer complaints” and provides several examples (emphasis added):

***“Product made my teeth worse with spacing and gaps...After five months and four aligners and a crack tooth and numerous attempts to talk to customer service to fix my issues all of which led nowhere.”***

***“Please don’t do this yourself—especially if you’re just trying to save money...my crown and implant- which was super expensive to get done- came off altogether.”***

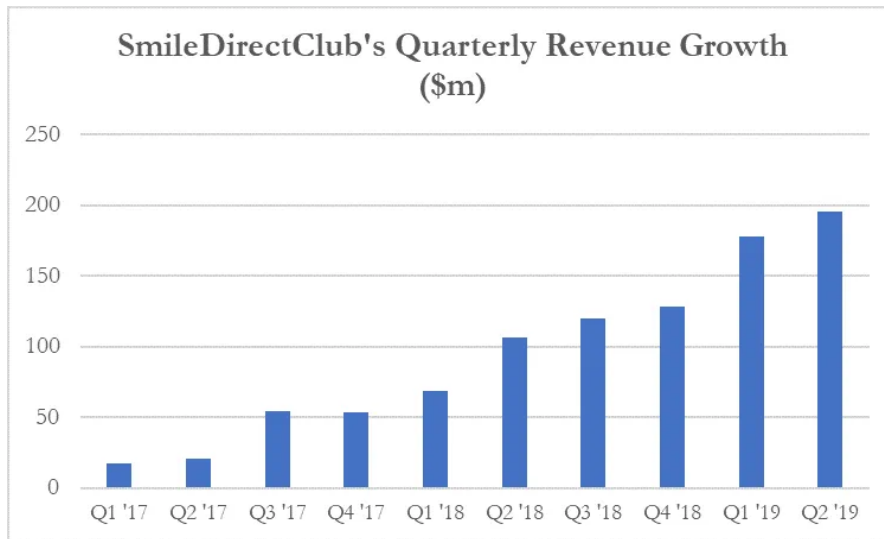
Similar complaints are ubiquitous across Facebook groups (1 (<https://www.facebook.com/groups/1757123961073804/>), 2 (<https://www.facebook.com/groups/404102996597815/>), 3 (<https://www.facebook.com/groups/smiledirectclub/>)) and review websites where SmileDirect customers share their stories, as we will show.

This is certainly not to say that *all* of the company’s customers are dissatisfied; after all, an assembly line approach to specialized dentistry can work for some, but it also creates dangerous gaps in the process that expose patients to heightened risks.

SmileDirectClub is taking the startup approach of “moving fast and breaking things”. In this case, unfortunately, they seem to be “breaking” many of their customers’ teeth.

## **Financials: Another Profitless Unicorn Incinerating Cash at an Accelerating Rate**

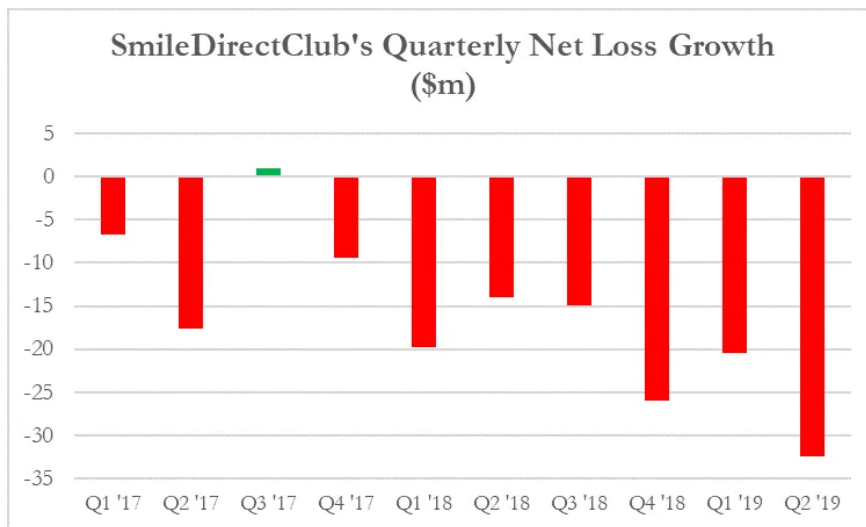
SmileDirectClub has seemingly focused on growing revenue at all costs. The company has seen an impressive revenue trajectory over the past 2 years, achieving 83% year over year revenue growth as of the most recent quarter:



(Source: Prospectus Pg. 90

(<https://www.sec.gov/Archives/edgar/data/1775625/000104746919005230/a2239665z424b4.htm>)  
)

But the company has *also* substantially increased its losses over the same timeframe:



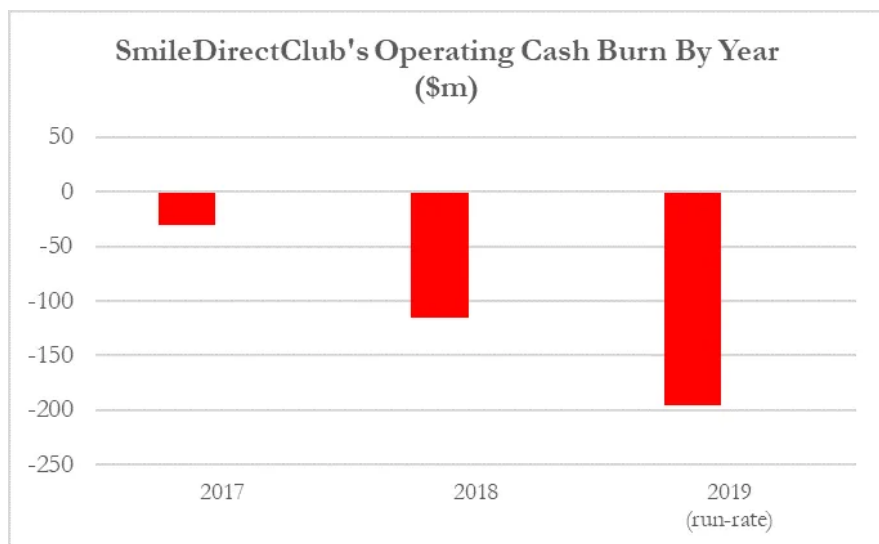
(Source: Prospectus Pg. 90

(<https://www.sec.gov/Archives/edgar/data/1775625/000104746919005230/a2239665z424b4.htm>)  
)

Note that the above GAAP losses could (we believe *temporarily*) improve in subsequent quarters. Last quarter, the company took a one-time \$29.6 million charge on the extinguishment of debt which it is not expected to repeat in subsequent periods.

The above losses are not fully reflected in the company's operating cash flow metrics, however, which are far worse. In the most recent 6-month period, the company used almost \$98 million of cash on an operating basis, putting it on track for a 2019 run-rate of negative \$196 million,

compared to negative \$114 million in 2018.



(Source: Prospectus Pgs. F-6, F-33

(<https://www.sec.gov/Archives/edgar/data/1775625/000104746919005230/a2239665z424b4.htm#GC>)

The cash flow metrics have suffered in part because the company has extended financing to roughly 65% of its customers, allowing them to pay over a period of up to 24 months [Pg. 34 (<https://www.sec.gov/Archives/edgar/data/1775625/000104746919005230/a2239665z424b4.htm>), 95].

We expect such financed revenue growth will represent a substantial future drag on cash intake, particularly with historical delinquency rates ranging from 9%-10%. [Pg. 34 (<https://www.sec.gov/Archives/edgar/data/1775625/000104746919005230/a2239665z424b4.htm>)]

The company has \$201 million in debt [Pg. F-47 (<https://www.sec.gov/Archives/edgar/data/1775625/000104746919005230/a2239665z424b4.htm#GC>)], the largest chunk represented by \$151.3 million drawn on its J.P. Morgan revolving credit facility (expiring December 14, 2020, unless renewed [Pg. F-49 (<https://www.sec.gov/Archives/edgar/data/1775625/000104746919005230/a2239665z424b4.htm>)])

With pro-forma cash of roughly \$537 million as of the IPO offering [Pg. 23 (<https://www.sec.gov/Archives/edgar/data/1775625/000104746919005230/a2239665z424b4.htm>)], an operating cash burn run-rate of \$196 million and \$151.3 million of debt due in 2020, we expect the company will aim to re-tap the equity markets by the end of 2020. That, of course, assumes the company's operating metrics stay on the same course.

## We Expect Financials Will Materially Worsen



We believe operating metrics will deteriorate in the future due to the company quickly approaching a “massive public backlash” stage of its business model. We believe that stage could include:

- **Major legal and regulatory liabilities.** As shown above, multiple state dental boards have already moved to outlaw some of the company's current practices. A major class action lawsuit was recently launched and we anticipate more will follow. The ADA and AAO also appear to be fighting the company's practices aggressively on all fronts.
- **Consumer backlash.** The backlash against companies that play it fast and loose with the public's health can be severe, as we have seen recently with vaping companies like Juul. We expect it is only a matter of time before the mainstream media sheds light on the subject of DIY orthodontics in the same manner.
- **Competition.** Even if *all* of the above was ignored, the company has no meaningful barriers to entry and well-funded competitors are emerging quickly.

## Part II: SmileDirectClub's Dangerous Lack of Professional Dental Oversight

Orthodontics is a specialized form of dentistry (<https://www.americanboardortho.com/orthodontic-professionals/about-board-certification/>). After a traditional 3 or 4 year dental program, dentists must then pass a rigorous exam and spend an additional 2 to 3 years in residency before earning orthodontic board certification (<https://www.americanboardortho.com/orthodontic-professionals/about-board-certification/>).

The reason orthodontists must spend additional years studying the craft is because orthodontics is both risky and patient specific.

The American Dental Association made this clear in their petition to the FDA (<https://www.ada.org/en/publications/ada-news/2019-archive/july/association-files-complaint-with-ftc-fda-against-smiledirect-club>) fighting against SmileDirect's practices:

*“Teeth are complex living organs comprising many elements. They have nerves and require blood circulation. Moving teeth that are next to other teeth, are rooted in bone, and are held in place by ligaments is often a complicated procedure dependent on multiple individual variables. There really isn't a “one-size-fits-all” methodology for providing competent, professional orthodontic treatment.”*

*-American Dental Association*

The genesis of most of SmileDirect's problems can be tracked back to what we believe to be a dangerous lack of professional dentist oversight.

We intend to walk readers through the traditional orthodontic process and show how it compares to SmileDirect's "disruptive" new process – and the dangers that result.

## **Orthodontic “Traditional” Model: It’s Essential to Have an Exam Before Orthodontics to Check for Dangerous Issues Patients May Be Unaware Of**

## **SmileDirect’s “Disruptive” Model: Instead of an Exam, We’ll Have Customers Self-Certify Their Dental Health and Sign A Waiver**

Dentists and orthodontists have been adamant that comprehensive oral exams are the required first step before undergoing orthodontics. The American Dental Association (“ADA”) has made this crystal clear (<https://www.ada.org/en/publications/ada-news/2019-archive/july/association-files-complaint-with-ftc-fda-against-smiledirect-club>) in its petition calling out SmileDirect’s practices:

*“Without a comprehensive oral examination, customers are at significantly higher risk for injuries attributable to their orthodontic treatment. This is why **dentists are ethically and professionally obligated to know firsthand, before they prescribe treatment, the state of their patients’ oral health.**” [Pg. 8 (<https://www.slideshare.net/secret/Fb6MHOigKskeic>)]*

The ADA further detailed the potentially severe consequences (<https://www.slideshare.net/secret/Fb6MHOigKskeic>) of ignoring this all-important first step:

*“...**patients may be severely injured, suffering tooth loss, bone damage, nerve damage, jaw pain, exposed teeth roots, receded gums, aggravated or entirely new bite maladjustments, and other related injuries.**” [Pg. 8 (<https://www.slideshare.net/secret/Fb6MHOigKskeic>)]*

Rather than following the industry standard, SmileDirect has seemingly chosen to ignore it. Instead, the company lets customers simply fill out a waiver and a survey stating whether they are aware of any dental issues.

We experienced this ourselves when we went to one of SmileDirect’s “Smile Shops” in Manhattan to research the intake process. There was no dentist on site at all.

At one point during the process, the assistant put an iPad in front of us with a 16-question survey of yes/no questions. **All of the answers were pre-filled out to say “no”**. Questions included:

- “Do you feel pain in any of your teeth?”
- “Have you noticed any loosening of your teeth?”
- “Do you have untreated periodontal disease?”

(See the full list of questions [here \(https://www.slideshare.net/secret/Jq0ZBbi7D4sWWW\)](https://www.slideshare.net/secret/Jq0ZBbi7D4sWWW))

Most people feel pain in their teeth at some point, but how many are able to accurately diagnose whether the cause is decay, or something else? Most people also don't even know what periodontal disease is, let alone the intricacies of testing for it.

This is likely why an orthodontist we contacted in Pennsylvania warned us that with teledentistry, we would be “skipping the most important step, **diagnosis**”. The orthodontist said that aligners require **“a full evaluation, and not just the signing of some waivers”**.

The outcome of SmileDirect's approach, as we will show, seems to involve a lot of broken teeth, damaged gums and other adverse outcomes, including worsening of gaps and bite issues.

## **Orthodontic “Traditional” Model: Carefully Screen Out Patients Who May Be Ineligible Due to Complications That Could Make the Process Dangerous**

### **Former SmileDirect Store Manager: My Entire Market Of “Smile Shops” Was Assigned Only One Actual Orthodontist, who “Cranked Out” 75 to 100 Cases Per Day from His Phone**

Once customers sign waivers and self-certify their own dental health, they seem to be fast-tracked down the SmileDirect assembly line.

We spoke to a former manager of one of the company's “Smile Shops” based in the Eastern United States, asking about the process for approving patients.

He told us that SDC had just one orthodontist for his **entire market of shops**, who would **“crank out”** about 75 to 100 case approvals or denials – *using his phone* – for those seeking treatment:

*"So we did have the orthodontist – his name was [redacted] – he would come by every once in a while, like maybe once a month, for like – he might do trainings about how to scan – but **he was getting things sent directly to his phone and he was making a determination on whether or not you'd be a good candidate or not.** So, he was very friendly, very helpful, very quick and efficient. We'd almost immediately see whether or not you would be a good candidate for this treatment."*

When we asked if the orthodontist was the only person responsible for approvals for his store, the ex-employee clarified that he **was in charge of the entire market** for his area:

*"One guy per market. So, some markets were a little bit different. We only had a couple of stores in the [redacted] market. He handled all of the ones that we had. **He's literally cranking them out, like as soon as we send them. It's taking him a couple of minutes and he's done.** And he can say 'yay' or 'nay'."*

Finally, when asked to estimate how many cases the orthodontist could go through on a daily basis, given the number his store was sending, combined with other stores in the market, the ex-employee said:

*"On a normal day, I'd say probably between 75 to 100."*

Obviously, there is a huge gap between personalized care from an orthodontist in their office versus an orthodontist who reviews a case as one of dozens (or possible hundreds) daily, **from his or her phone.**

## **SmileDirect's Aggressive Sales Culture: Employee Review Claims "We Are Approving Too Many Cases That Should Never Be Allowed"**

A common theme among online reviews is that SmileDirect takes on patients that are rejected by competitors like Invisalign and traditional orthodontists.

On Glassdoor (<https://www.glassdoor.com/Reviews/Smile-Direct-Club-Reviews-E1043560.htm>), employee reviews (1 (<https://www.glassdoor.com/Reviews/Employee-Review-Smile-Direct-Club-RVW29100896.htm>), 2 (<https://www.glassdoor.com/Reviews/Smile-Direct-Club-SmileGuide-Reviews->

El IE1043560.0,17\_KO18,28.htm),3 ([https://www.glassdoor.com/Reviews/Smile-Direct-Club-Reviews-E1043560\\_P13.htm](https://www.glassdoor.com/Reviews/Smile-Direct-Club-Reviews-E1043560_P13.htm))) describe how an aggressive sales culture contributes to dangerous approvals at SmileDirect's Smile Shops (emphasis added):

*"You are appointed 30 minutes to sell a new smile to each new customer all day every day and then next customer. Your job is only secure based on you selling and closing at least 70%+ during these appointments each month, using all the newest sales tactics the company keeps pushing us to use. That is company standard and you will be put on a PIP and performed out if you cannot meet their sales expectations. "*

***"This is hard to do with a clear conscience once you see refinement and midcourse correction customers coming into our shops DAILY with serious mal-occlusion, open anterior bites, edge to edge occlusion, and even mobility due to treatment! We are approving too many cases that should never be allowed to do ortho without a doctor evaluating their periodontal health or being UPFRONT and STRAIGHT FORWARD with how their bites will be misaligned once treatment is completed. We are not doing the right thing for everyone. Yes, we are helping many people achieve the smile of their dreams, but others are being ruined. I see those people daily!"***

Based on multiple reviews, agents are tasked with closing sales on 70%-73% of their appointments. This raises the obvious question: what if 70% of an agent's initial appointments aren't eligible for SmileDirectClub due to obvious dental issues?

## **SmileDirect's Aggressive Sales Culture: We Filled Out the Company's 'Smile Assessment' Saying "I Have Zero Teeth Left in My Mouth"**

### **SmileDirect's Response: "You're a Great Candidate!"**

A quota sales system puts numbers over quality, which can be dangerous in a medical context.

High quotas also strike us as extremely inadvisable given that SmileDirect's **initial sales funnel doesn't seem to reject anyone**. We filled out the company's "30 second smile assessment" ([https://smiledirectclub.com/smile\\_assessment/](https://smiledirectclub.com/smile_assessment/)) on its website and noticed that we got accepted as a "great candidate" no matter what answers we provided.

Eventually we put the company's assessment to the ultimate test, declaring "I have zero teeth left in my mouth".

# Free 30-second Smile Assessment

Take 30 seconds to answer these questions and find out if SmileDirectClub is right for you.

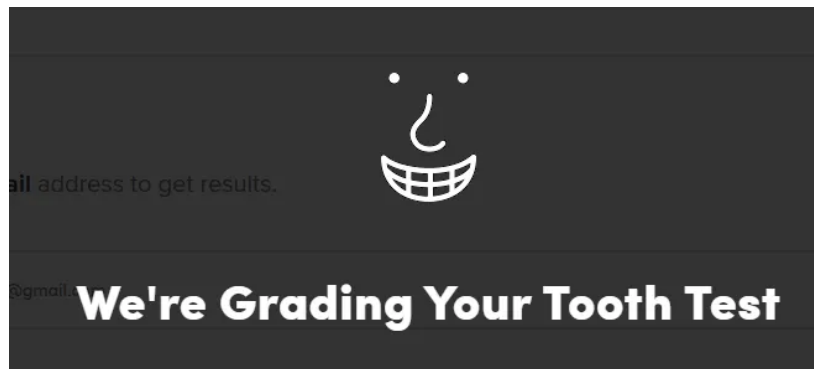
Why are you thinking about straightening your teeth?

Other: Please specify

Other:

I have zero teeth left in my mouth.

After "grading our tooth test..."



SmileDirect determined that we were a great candidate!

CONGRATULATIONS!

## You're a great candidate.

Get started on the smile you'll love in just three easy steps.

The reputation for accepting just about anyone (even in later stages of the process) pervades online reviews about the company, as well. In one example, a customer says:

*"Other companies rejected me, yet I was accepted by SDC...(my teeth are) pretty crowded, and was surprised that they accepted me."*



██████████ Pretty much same story for me.  
Invisalign was recommended, but not affordable.  
Other companies rejected me, yet I was accepted by SDC.  
So far, so good.  
I'm currently on M2W2 and I'm seeing very small improvements.  
  
The photo is before treatment.  
I'm pretty crowded, and was surprised that they accepted me.

The user later posted this photo of her teeth in the thread:

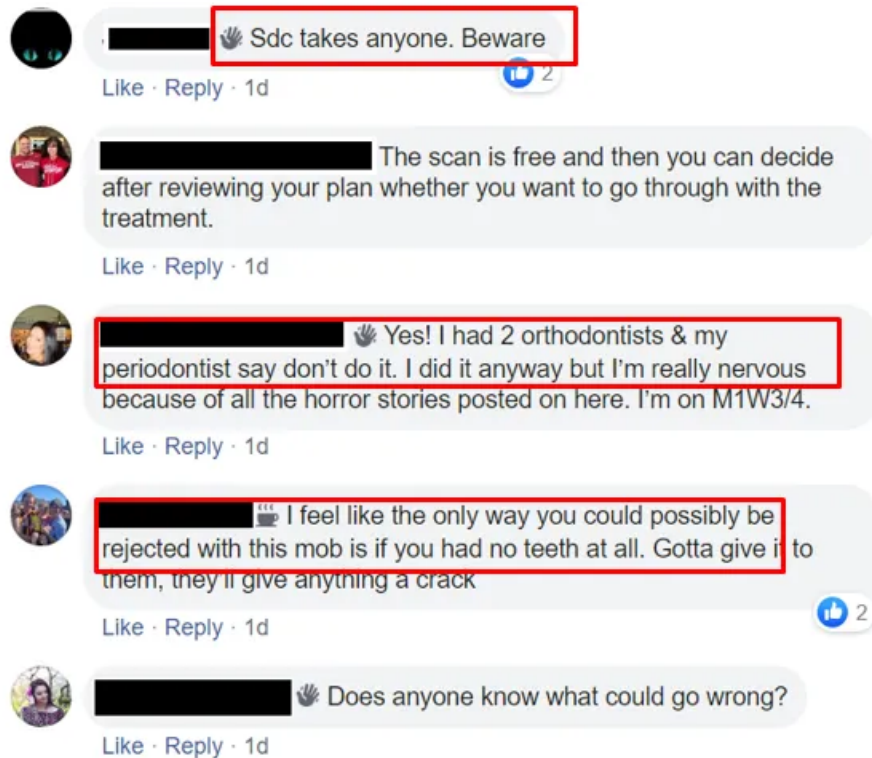


██████████  
I hope so, my teeth are worse than yours.  
I'm sure you'll get good results.  
This is another pic at how bad they are.



The thread continued, with users warning that Smile Direct takes anyone.





The former store manager we spoke with estimated that the orthodontist approved about 80% of cases in his market.

We reached out to the company asking for the overall approval/denial rate. We will update this report should they write back with an answer. (See Appendix A for all the questions we asked the company and for our somewhat odd interaction with investor relations.)

Overall, the company's aggressive sales culture, quota system, and practices seem to encourage treating patients that have clearly been deemed unsuitable by the "traditional" orthodontic model.

## **Orthodontic "Traditional" Model: Trained Professionals Take Your Dental Scans in A Sterile Office in Case Anything Goes Wrong**

## **SmileDirect's "Disruptive" Model: We'll Mail You Dental Impression Molds and You Can Perform this Important Medical Procedure in Your Living Room**

Traditionally, once a patient is pre-screened for treatment, professional dentists/orthodontists take impression molds or perform a scan of their patient's teeth. With the benefit of experience, professionals can take more effective impressions or scans and can avoid common dangers and pitfalls.

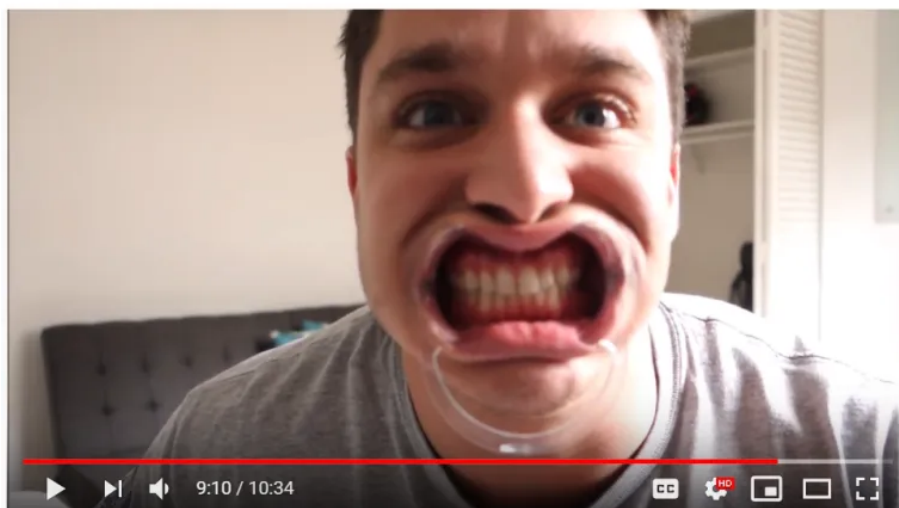
Contrary to the approach of using experienced professionals, SmileDirectClub mails customers impression molds and instructs them how to do it themselves. Here is one (of several) [YouTube videos](https://www.youtube.com/watch?v=3u2Kl9MpheY) (<https://www.youtube.com/watch?v=3u2Kl9MpheY>) of a SmileDirectClub customer trying to figure out the at-home process:



Smile Direct Club Impression Kit - At Home Dental Impressions

(<https://www.youtube.com/watch?v=3u2Kl9MpheY>) Following the molds, the company then instructs customers to take pictures of their teeth.

It is hard to imagine that these pictures and impressions, performed almost entirely by untrained first-time customers using their phones in their living rooms or bathrooms, are of the highest quality.



Smile Direct Club Impression Kit - At Home Dental Impressions

Nonetheless, the pictures and impressions, which serve as the foundation of the process for many of SmileDirect's customers, are **then sent to offshore unlicensed technicians based in Costa Rica** to set up treatment plans. (Yes, we're serious. More on this later.)

We asked an orthodontist about whether taking impressions was really all that hard:

*"How difficult is it to take accurate impressions? Would you trust someone who has never done it before to take them?"*

His response:

*"Very. Never. Even highly skilled dental assistants occasionally make poor impressions, necessitating retakes."*

## **Orthodontic "Traditional" Model: In Case Any Issues Crop Up with Your Impressions, You Are in a Doctor's Office Surrounded by Professionals**

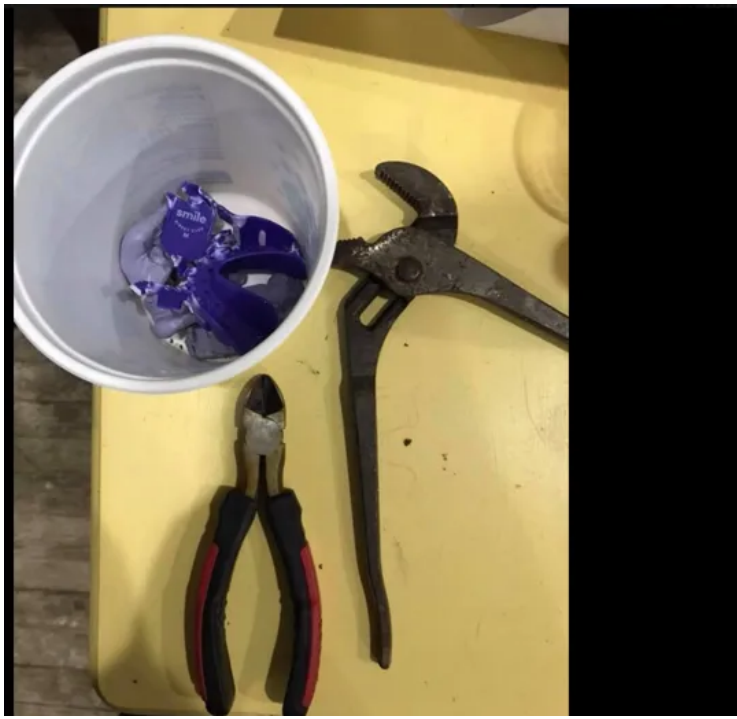
## **SmileDirect's "Disruptive" Model: Customers Cutting Molds Off with Wire Cutters and Other Horror Stories That Result from DIY Dentistry**

Sometimes medical procedures go wrong even under the care of professionals. But when medical procedures go wrong at home, users are generally unprepared.

We read multiple online reviews from SmileDirect customers whose impression molds got stuck. The customers then needed to find various ways to pry the molds free from their mouths.

In other instances, the untrained customers simply took bad impressions, which they believed led to bad aligners that either didn't fit at all or worse—led to damage or other adverse outcomes.

In one example, a user had his molds get stuck in both his gums and a bracket he had for a missing tooth. After running around in a panic for 30 minutes, **unable to breathe**, the individual was forced to take emergency dentistry into his own hands, **cutting the mold out of his mouth with wire cutters**.



September 21, 2018 ·

I don't usually start anything bad and bad call a company but trust me this is bad. I decided to use the smile direct club to help fix my teeth, just a small fix nothing bad but maybe a month or two of retainers. I decided this week to go through with the payment and order the kit to send back to smile direct club. Got the kit today and planned to go Monday before class to send it back. Top impressions went perfectly and I was smiling and was glad I can get this fixed. Then came bottom to get it impressed. I did everything correct and had waited til I can pull it off. Fun part came after this. The mold got stuck in my gum and bracket for my missing tooth. After almost 30 mins of running around with drool coming out of my mouth, I had to grab my tools from my tool box and cut this mold into a bunch of little pieces. I could not breath due to the mold pushing down on my tongue. So to people who think doing the smile direct club is better than braces trust me go the more expensive route because this did not go well at all. If it was not for smart thinking I would have messed my teeth up even more.

Per the Facebook post ([https://www.facebook.com/search/top/?q=ethan%20wade%20heacock&epa=SEARCH\\_BOX](https://www.facebook.com/search/top/?q=ethan%20wade%20heacock&epa=SEARCH_BOX)) (emphasis added):

*"Top impressions went perfectly and I was smiling and was glad I can get this fixed. Then came bottom to get it impressed. I did everything correct and had waited til I can pull it off. Fun part came after this. The mold got stuck in my gum and bracket for my missing tooth. **After almost 30 mins of running around with drool coming out of my mouth, I had to grab my tools from my tool box and cut this mold into a bunch of little pieces. I could not breath due to the mold pushing down on my tongue.**"*

*"So to people who think doing the SmileDirectClub is better than braces trust me go the more expensive route because this did not go well at all. If it was not for smart thinking I would have messed my teeth up even more."*

We followed up with the individual and asked him for more information about the experience. He told us:

***"Yea I had to cut the mold off with a pair of wire cutters. I did my research before I even purchased the kit to make sure that the bridge my dentist inserted would not interfere with the molding. I could not get the molding off at all. It had actually seeped below my bridge and was stuck it actually got so bad I had to resort my way into cutting near my gum line just to free my bridge from it getting ripped out."***

We remarked offhandedly that “hopefully you at least got your money back” and received this unexpected reply:

*“Actually no to this day and this was a year ago actually. To this very day I still get calls, texts and emails telling me I need to turn in the moldings. I had actually called them plenty of times and even sent that very picture and told them hey it got stuck and this is what’s left of it and they said it was not their problem and that they needed some broken molds back”*

## **Orthodontic “Traditional” Model: In Case Any Issues Crop Up with Your Scans, You’re in a Doctor’s Office Surrounded by Professionals**

### **Smile Shop In-Store Horror Stories: “There Were Many Instances Where, In the Middle of a Scan, A Customer’s Tooth – Or Teeth – Came Out. And There Would Be A Lot of Blood.”**

These days, digital scanners are much more common than using impression molds. Per an orthodontist we communicated with:

*“All orthodontists now use digital scanners in their offices. A digital scan is much more accurate. In New York State, only a certified dental assistant, or doctor, is permitted to make a digital scan for the purpose of fabricating a medical device.”*

SmileDirect offers digital scans (in lieu of at-home mold kits) for customers that can make it to any of the company’s roughly 300 brick & mortar Smile Shops. [Pg. 2 (<https://www.sec.gov/Archives/edgar/data/1775625/000104746919005230/a2239665z424b4.htm>)] But even in this environment, the Shops generally do not have a trained dentist or orthodontist on site, instead relying on dental assistants or dental hygienists for support.

A former “Smile Shop” store manager shared some of his most difficult experiences with us. Among those horror stories, were times when customers would lose a tooth – **or teeth** – in the midst of getting a scan to see if they were eligible for SDC.

As the former store manager told us, he wasn’t a dentist, so he was left unsure of what to do (emphasis added):



*"There were many instances where, **in the middle of a scan, a customer's tooth came out – or teeth would come out. And there would be a lot of blood** – and both instances are not something that you really can prepare for."*

*"And it would be traumatic for our Smile Guides to have to deal with that, even though a lot of them did come from, or had dental backgrounds or worked in dental offices. You know, it's a very unpleasant experience. You have to deal with something like that – like, **I'm not a dentist – what do I tell you?**"*

Customers that lost teeth in the store generally had issues with loose teeth and gums that would normally preclude them from orthodontics to begin with. Once again, the issue seemed to arise from a lack of screening procedures and a lack of oversight from a dentist.

## **Orthodontic "Traditional" Model: Once Your Dentist/Orthodontist Determines You Are Eligible and It's Safe, They Will Craft Your Plan and Guide You Along the Way**

## **SmileDirect's "Disruptive" Model: Onshore Dentists are Allegedly Paid a Token \$50 Per Each 'Approved' Treatment Plan, While Plans Are Set up Offshore by Unlicensed Technicians in Costa Rica**

SmileDirect states that a U.S. licensed dentist "approves" the patients and their treatment plans. This is true, but according our conversations with former employees and a recent class action lawsuit, such approvals appear to be mere token involvement.

The [complaint](https://www.slideshare.net/secret/cMSW7zDYrbw1UA) (<https://www.slideshare.net/secret/cMSW7zDYrbw1UA>) alleges that onshore dentists are paid a small \$50 flat fee *per approval*:

*"SmileDirect states that a U.S. licensed orthodontist 'approves' the treatment plan. In fact, to the extent that U.S. doctors or orthodontists are involved in the process, they are minimally involved. SmileDirect has acknowledged in its 'ELP participation agreement for 2017' that, **to the extent a U.S. dentist "participates" in approving the treatment program, they are only paid if they actually approve the program and then are paid only \$50.**"*

The ADA petition to the FDA lambasting SmileDirect also references this price point per approval as well. [Pg. 19 (<https://www.slideshare.net/secret/Fb6MHOigKskeic>)]

We reached out to SmileDirect to confirm whether this is still in fact the process and will update this report should they write back with an answer.

SmileDirect also does not use onshore licensed medical professionals to set up treatment plans. **Rather, the company conducts all of its treatment planning operations in Costa Rica.** [Pg. 31 (<https://www.sec.gov/Archives/edgar/data/1775625/000104746919005230/a2239665z424b4.htm>)]

**The company employs “approximately 650 treatment plan setup technicians” in Costa Rica along with “approximately 85 doctors for quality review”.** [Pg. 115 (<https://www.sec.gov/Archives/edgar/data/1775625/000104746919005230/a2239665z424b4.htm>)]

Once the plans are set up and reviewed offshore, an onshore dentist is then sent the plan for approval.

All told, this staggered, assembly line approach to the process seems to preclude meaningful doctor/patient interaction. It makes it difficult to fathom how the actual licensed dentists are much more than a rubber-stamp along the way.

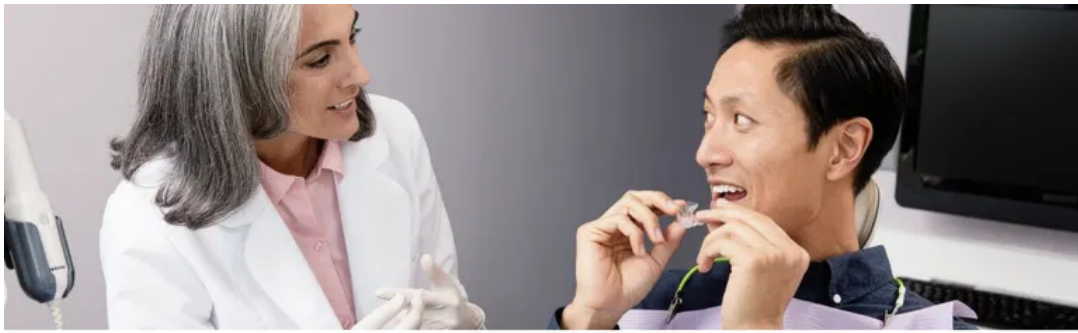
## **Orthodontic “Traditional” Model: Dentists Fit New Sets of Aligners on Patient in Office Making Sure They Do Not Damage the Mouth**

## **SmileDirect’s “Disruptive” Model: Aligners Shipped Directly to Patients, Who Make Adjustments at Home with Tools Like Nail Files**

Traditionally, during clear aligner treatment (the type of product SmileDirect offers), aligners are shipped to the dentist supervising the patient. From there, professionals ensure a proper fit and that the aligners do not cause damage to the patient’s jaw, teeth, or gums. The visit also gives patients a dedicated doctor to answer questions and guide them along the way.

See below for how SmileDirect’s largest competitor, Invisalign handles the protocol (<https://www.invisalign.com/how-invisalign-works/starting-treatment>):





Your smile is in  
good hands

It's the first day of your new smile and time to pick up your first aligners at your doctor's office. This is a key step in your success. With Invisalign treatment, you're never on your own.

When you pick up your first aligners, your doctor will:

- Ensure your aligners fit well
- Answer your questions
- Let you know what to expect

(Source: Invisalign (<https://www.invisalign.com/how-invisalign-works/starting-treatment>))

Contrary to that guided procedure, SmileDirect sends aligners to its customers by mail. From there, customers regularly take matters into their own hands when the aligners don't fit or cause bleeding or other damage.

SmileDirect groups and message boards are littered with customers advising each other on DIY dentistry topics like which nail files to purchase to file down their aligners and how to adjust aligners at home:



[REDACTED] shared her first post.

👤 New Member · Yesterday at 7:08 AM

I am just starting with SDC. I'm having a BIG problem removing my aligners. It feels as if I'm going to pull my teeth to take them out. So much so that I am afraid to put them back in. I have noticed that they are higher up on my gums on one side. I sent a message to the SDC, and they were extremely nice. I don't think they ever understood my question though. Is this typical? On some videos I've seen where people had to file aligners. Is this recommended? I'm frustrated to the point I'm thinking of getting a refund.



1

42 Comments



Like



Comment

View 10 more comments

[REDACTED] <https://www.walmart.com/.../Equate-Beauty.../147386256...>

Buy this.



WALMART.COM

Equate Beauty Equate Total Nail Care System - Walmart.com



1

Like · Reply · 23h



[REDACTED] shared her first post.

👤 New Member · 1 hr

Hi all! I'm on M4W3 and i noticed my gums start to bleed every time i take them out the ones on top behind my teeth/ by roof of mouth. Is this normal?



1

4 Comments



Like



Comment



[REDACTED] Mine too. You might have to file a little there where it digs in.

Like · Reply · 1h



[REDACTED] i did that. I'm wondering if it has to do with how much my teeth have closed and possibly pushed my gums back and is squishing them ?

Like · Reply · 56m



[REDACTED] possibly 😬 I need to file mine Tonight, I hope it helps 😊

Like · Reply · 53m



[REDACTED] I'll file some more! Lol thank you 😊

Like · Reply · 31m



We asked one orthodontist “Why do aligner fittings in an office instead of just shipping aligners to patients?”

His reply: **“Moving teeth is not a benign process. It’s a medical procedure.”**

## **Former SmileDirectClub Employee: Customers Are Under the Impression That The “Dental Team” Consists of Dentists or Orthodontists, But the Only Requirement is to Be a Dental Hygienist or Dental Assistant**

When SmileDirect customers have medical issues, they can contact customer service, which puts them in touch with the company’s “Dental Team”.

We spoke to a former SmileDirect customer service representative as part of our research who informed us that customers are often under the mistaken impression that the Dental Team consists of dentists.

Instead, we were told that the only requirement to be on the “Dental Team” was to be a dental assistant or dental hygienist (emphasis added):

*"The dental team is the ones who actually talk on the phone with customers...If you're a dental assistant or dental hygienist, you can be on the dental team. And that's not saying that they're the ones creating the plan. **But they're the ones that are on the phone talking to the people who are pretty much under the impression that they're a dentist or orthodontist.**"*

Once again, SmileDirect customers hoping for medical advice from a dentist seem to be under the wrong impression.

## **Former SmileDirectClub Employee: Customers Are Only Given the First Name of People They Speak to on the "Dental Team"**

Part of the reason customers are under the wrong impression about the Dental Team is because they are provided very little information about who they are speaking with. We were told that **customers are essentially kept in the dark:**

*"Really, the only information that they have is their first name...whenever they talk to people, there was never a direct line for a direct person specifically. The only email or number for the dental team was the generic [DentalTeam@smiledirectclub.com](mailto:DentalTeam@smiledirectclub.com) (<mailto:DentalTeam@smiledirectclub.com>) and then all the calls went to the same number, if that makes sense."*

The former representative continued, telling us the only place customers got a name was the one that was appended to their Smile Plan, and that even as an employee of the company they were largely in the dark about names of people on the Dental Team (emphasis added):

*"There's a person's name on their Smile Plan, which is basically what was created for their smile for the invisible aligners, but that's like really the only place that there's a name."*

*"But they definitely didn't have any information that showed 'this person practices in this state', you know what I'm saying? Because of insurance purposes, I know they did have to categorize it by location, but we didn't really see any of that at all. **The only thing I could ever see was the name of the person that created the plan, that was really it. And that's really, I think, the only thing that the customer was really able to see as well.**"*

In the American Dental Association's petition to the FDA (<https://www.regulations.gov/document?D=FDA-2019-P-2038-0001>) regarding SmileDirect, it writes:

*"To any extent SDC may have lowered costs it has done so by recklessly selling "do-it-yourself dentistry" over-the-counter to its customers..."*

*"SDC has virtually eliminated from the process any substantive participation by a dentist in a customer's teeth straightening treatment"*

## **Part II Conclusion: When Specialized Medicine Meets Assembly Line**

On SmileDirect's website its "Lead Dentist" states (<https://smiledirectclub.com/blog/doctors-behind-your-smile/>):

*"An individual who is requesting treatment by using SmileDirectClub's aligners is receiving the same level of care from a treating dentist or orthodontist as an individual visiting a traditional orthodontist or dentist for treatment."*

*– Jeffrey Sulitzer, DMD, Lead Dentist at SmileDirectClub*

The above statement seems to be the key to SmileDirect's "success". Meanwhile, every dentist or orthodontist that we spoke to disagreed with this statement.

We think consumers, regulators, and the media will soon wake up to the realization that this assertion made by the company is wrong at every turn.

## **Part III: An Unhealthy Habit of Using Litigation to Squelch Criticism, Competition Emerging, Governance Questions, and Insiders Cashing Out**

### **Want a Refund? First Sign This Legal Release Saying You Won't Post Negative Online Reviews and Won't Complain to Regulators**

One of the key selling points for SmileDirect seems to be its customer review ratings. Third-party review sites show ratings ranging from 2.7 (<https://www.highya.com/smiledirectclub-reviews>) to 4.3 (<https://www.trustpilot.com/review/smiledirectclub.com>) out of 5.0 stars. The company claims in its

prospectus that it has an average rating of 4.9 out of 5.0 from user reviews submitted through its own website. [Pg. 2

(<https://www.sec.gov/Archives/edgar/data/1775625/000104746919004785/a2239489zs-1.htm>)]

In examining the company's reviews, we found a troubling fact.

When most normal companies have an unhappy customer, they grant a refund or make other concessions. Rather than follow that typical practice, SmileDirectClub seems to turn its refunds into hush money.

The Capital Forum recently reported that SmileDirect withholds refunds to dissatisfied customers unless they sign agreements not to post negative reviews or file regulatory complaints. Per the article (<https://thecapitolforum.com/wp-content/uploads/2019/07/SmileDirectClub-2019.06.21.pdf>):

*"Customers who are dissatisfied with their experience and want a refund are asked to sign a release preventing them from filing negative complaints on social media or with regulators and to withdraw any previously filed complaints. This practice could run afoul of Section 5 of the FTC Act and state laws, according to FTC staff and legal experts."*

Again, we're not saying the company doesn't have happy customers. The product clearly works for some. Nonetheless, these attempts to muzzle negative reviews strikes us as a method of distorting reality.

## **SmileDirectClub's Pattern of Using Aggressive Litigation to Silence Criticism: This is the Worst that Capitalism Has to Offer**

Beyond its attempts to muzzle dissatisfied customers, the company has filed a bevy of lawsuits (<https://www.buzzfeednews.com/article/nidhisubbaraman/smile-direct-club-lawsuits-dentists>) against critics.

We at Hindenburg take pride in reporting on companies that try to use litigation to silence criticism. We believe that companies engaging in such practices are vastly more likely to have something sinister to hide.

- In late 2017, the company sued an orthodontist (<https://www.slideshare.net/secret/mGtoU5xdclQsxA>) who posted a YouTube video that questioned the safety of the company's approach. The parties later settled (<https://www.slideshare.net/secret/lkR5FBZ4R8U1x>).



- Days later, it sued the Michigan Dental Association (<https://www.slideshare.net/secret/HLqVPYt8yK8kxe>) for writing an article about SmileDirect that highlighted “numerous legal and patient safety concerns.” The case was eventually dismissed (<https://www.slideshare.net/secret/3FY7wt95M7Aie2>).

In addition to suing critics, the company has used the threat of litigation to intimidate others from coming forward.

A recent complaint (<https://www.slideshare.net/secret/cMSW7zDYrbw1UA>) alleged “a barrage of ‘cease and desist’ letters from SmileDirect’s counsel threatening lawsuits and threatening the filing of ethical complaints with regulators” against professionals that had voiced their opinions on the inadequacy of the product.

All told, we think the pattern of lawsuits, threats, and muzzling of dissatisfied customers are all telltale signs that SmileDirect is a company that goes out of its way to silence opposition.

## **No Meaningful Barriers to Entry: Well-Funded Competitors Are Popping Up Left and Right**

Despite the company’s aggressive practices, it has burned significant cash and has printed significant net losses to date.

Even if one were to assume that the public, regulators, and the company’s customer base raise no issues with its practices (which they are), basic economics would nonetheless make it incredibly hard to achieve lasting profitability going forward.

We are already seeing numerous competitors to SmileDirect offering substantially similar services:

- Invisalign (<https://www.invisalign.com/>) (founded in 1997 (<https://www.johnsoneliteortho.com/the-history-of-invisalign/>))
- Uniform Teeth (<https://www.uniformteeth.com/>) (founded in 2015 (<https://www.crunchbase.com/organization/uniform-teeth#section-overview>))
- Orthly (<https://www.orthly.com/>) (founded in 2016 (<https://www.crunchbase.com/organization/orthly#section-overview>))
- Candid (<https://www.candidco.com/>) (founded in 2017 (<https://www.crunchbase.com/organization/candid-4#section-overview>))
- Smile Love (<https://smilelove.com/>) (founded in 2017 (<https://www.crunchbase.com/organization/smilelove#section-web-traffic-by-similarweb>))
- SnapCorrect (<https://snapcorrect.com/>) (founded in 2017 (<https://www.linkedin.com/in/luis-lajous-2620667/>))
- Byte (<https://www.byte.me/?campaignid=1855444742&adgroupid=69575475963&adid=346745637359&gclid=CjwKCAjwldH>



sBRAoEiwAd0JybVI7pN6evhU4kGgM7YpgjOG0Ls1hDKXXbFdNdKPbK6GvHkdNbckVMxoCp1MQ.  
AvD\_BwE) (founded in 2017 (<https://bestcompany.com/invisible-braces/blog/smiledirectclub-vs-byte>))

We spoke to Candid, Invisalign, Smile Love, Uniform Teeth, and Orthly. The most commonly cited differentiator relative to SmileDirect was that the competitors included substantial involvement from an orthodontist throughout the process, often including multiple visits and direct guidance.

The competitors cited SmileDirect as a mostly Do It Yourself (DIY) operation with very light involvement from orthodontists.

SmileDirect has spent an enormous amount on marketing to date (\$209 million in marketing & selling expenses in just the past 6 months! [Pg. 88

(<https://www.sec.gov/Archives/edgar/data/1775625/000104746919005230/a2239665z424b4.htm>)]

In the absence of meaningful barriers to entry, the company may simply be paving the way for more responsible competitors to take its market share.

## **Governance Questions: Chairman/CEO Sold his \$3.4 Million Private Plane to the Company 1 Month Prior to the IPO. And It Wasn't Even the First Time He Sold an Interest in a Private Plane to the Company!**

SmileDirect's Chairman David Katzman controls about 87.5% of the vote [Pg. 150

(<https://www.sec.gov/Archives/edgar/data/1775625/000104746919005230/a2239665z424b4.htm>)],

giving him extraordinary power.

With that power, some of his recent decisions strike us as questionable. Namely, in August 2019, one month before the IPO, Katzman's entity sold the company his 1996 twin-engine private jet for \$3.4 million. [Pg. 156

(<https://www.sec.gov/Archives/edgar/data/1775625/000104746919005230/a2239665z424b4.htm>)]

Here is the plane (<https://flightaware.com/resources/registration/N623HD>):



Remarkably, **this wasn't even the first time Katzman sold the company a plane.** In February 2019, the company purchased a \$1.1 million interest in another plane from a Katzman-controlled entity. [Pg.156  
(<https://www.sec.gov/Archives/edgar/data/1775625/000104746919005230/a2239665z424b4.htm>)]  
In 2018, a Katzman entity billed the company roughly \$1 million for use of his plane.

## Governance Questions: Executives and Affiliates Offloaded Almost \$700 Million Into the IPO

In an IPO, investors aim to see cash reinvested back into the business to have a growth profile to look forward to.

We're also realists – it's reasonable to expect some insiders and early investors to want to cash out parts of their stakes.

During SmileDirect's IPO, company executives and affiliates cashed out almost \$700 million, **representing over half of the total net IPO proceeds:**

	Class A common stock to be Purchased	Aggregate Purchase Price
David Katzman(a)(d)	8,998,951	\$ 198,411,369
Jordan Katzman(b)(d)	7,141,516	157,462,872
Alexander Fenkell(c)	6,521,446	143,790,803
Steven Katzman(d)	663,595	14,500,839
Susan Greenspon Rammelt	29,964	654,713
CD&R SDC Holdings, Inc.	2,275,857	49,727,475
Other(e)	5,990,646	131,941,093
<b>Total</b>	<b>31,621,975</b>	<b>\$ 696,489,166</b>

(Source: Prospectus Pg. 153

(<https://www.sec.gov/Archives/edgar/data/1775625/000104746919005230/a2239665z424b4.htm>)  
)

By comparison, only \$387.9 was raised for general corporate purposes, with the balance paying yet more executive bonuses and cashing out early shareholders.

All told, we think the company's executive team chose pinpoint timing to offload their shares onto the public (*and* a couple of private jets).

## Conclusion & Predictions

We think SmileDirect is selling a dangerous product that cuts corners instead of actually disrupting the orthodontics industry. True disruption results in a better product at a better price, not in muzzling harmed customers with legal releases and silencing critics with litigation.

We expect SmileDirect's harmful practices will lead to an increasing chorus of opposition from regulators, media, customers, and its more responsible competitors, eventually impairing its brand or forcing it to significantly alter its practices. This won't happen instantly, but we think within a year we'll be looking at a vastly different "teledentistry" landscape than we are right now.

As far as the stock is concerned, the company is currently trading at ~6.5x its current revenue run-rate, despite continuing to incinerate cash. The market is currently valuing SDC as if it is a high-margin recurring-revenue SaaS company in explosive-growth mode.

In reality, SDC strikes us as (i) a low-quality consumer product company (ii) with high customer acquisition costs (iii) in a competitive, worsening-margin environment (iv) extending seemingly sub-prime financing to customers (v) who are largely making 1-time purchases.

The company's ridiculous valuation is typically only found deep in the enchanted unicorn forests of Silicon Valley. Now that SDC is a public company, we expect its valuation will become far more tethered to actual operating performance over the next 6-12 months as IPO lockups expire and as the market begins to process its business model.

We expect that the company will continue to show revenue growth, and may even turn a brief GAAP profit, while continuing to burn operating cash flow over the next couple of quarters.

Given our prognosis for negative cash flow and negative net income, we were left with a basic revenue multiple for our analysis. When applying a 2x multiple to SDC's Q2 2019 revenue run-rate we arrive at a market cap of \$1.5 billion, representing downside of 70%.

As consumer backlash hits, and the company's cash balance comes back into focus, we expect matters to worsen considerably. Our overall 12-month price target is \$2, representing about 85% downside from current levels.

Best of luck to all.

## **Appendix A: Questions We Asked the Company**

We emailed SmileDirect's investor relations with questions in advance of this report. They replied quickly (A+ response time), but repeatedly asked that questions be answered over the phone. We repeatedly asked that they answer questions, any of them, in writing (we wanted them to be definitive/on-the-record) and they failed to do so. We found the exchange to be pleasant, though rather odd.

Should the company respond back with answers to any of our questions below, we will update this piece accordingly. Here they are so readers can get a sense of the questions we were interested in:

1. What do you view as the next growth market for the company? I saw some expansion in the UK but where else do you see opportunities in the near future?
2. I read in the recent class action complaint which said that Alabama and Georgia had outlawed certain practices employed by the company. Are you receiving pushback from any state boards other than Georgia and Alabama right now? How do you plan to handle operating in those two states going forward?
3. Have you heard any guidance or response from the FDA or FTC on the issues raised by the ADA with those agencies?
4. One common criticism I've seen is that the company doesn't have thorough involvement from orthodontists and dentists. What is the role of dentists/orthodontists in the SDC process from start to finish?
5. Do customers know who they are speaking with on the dental team?
6. Who do you see as your most formidable competitor at the moment?

7. What percentage of prospective customers does the company reject?
8. The recent class action lawsuit stated that the company pays orthodontists/dentists \$50 per approval of each plan. Is that still the going rate today?
9. Are there other circumstances where orthodontists/dentists are paid and what are the rates for those services?
11. The Capital Forum published an article recently saying that customers are asked to sign a release in order to get a refund. Is that still the case and are you able to share a copy of what that release looks like?
12. What percentage of aligner sales are generated from at home kits vs SmileShop scans? Do you see that mix changing?

## Disclosure & Legal Disclaimer

### Disclosure: We are short shares of SmileDirectClub

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 **John Sabastian** says:

October 4, 2019 at 2:26 pm (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/#comment-32812>)

How much is big ortho paying you for this trash? A \$2 price target for a company that has completely stolen the largest sector of Align Technoloy's business. Go Check their stock over the past year since competing with a fully ramped SDC. More shorting trash analysts.

Reply (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/?replytocom=32812#respond>)

 **Kelthius** says:

December 13, 2019 at 3:24 pm (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/#comment-33281>)



You're poor so you have to order mail order medical work lmao. I went to a real ortho and paid 4 grand for my braces. I go in every week for fittings. That's why mail order braces you idiots teeth get jacked up even more.

Reply (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/?replyto=33281#respond>)



**Redqueen87** says:

January 2, 2020 at 4:45 pm (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/#comment-33423>)

That's like so totally super duper cool that you can afford to throw money out on stuff like that, BUT not everyone does so you shouldnt be so quick to judge or make fun of anyone who isn't in your position OF NOT HAVING TO WORRY ABOUT ANYTHING FINANCIALLY MORON

Reply (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/?replyto=33423#respond>)



**Dr ortho will not leave my name due to litigious SDC** says:

October 5, 2019 at 7:02 am (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/#comment-32827>)

Wow. Article spot on.

I'm an orthodontist and you've done a great job researching this.

Reply (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/?replyto=32827#respond>)



**Paul Tudor Jones** says:

November 22, 2019 at 4:43 am (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/#comment-33129>)

"a company that attempts to fit a complex, dangerous medical process" such misinformation, how is fixing crooked teeth dangerous? Hindenburg Research will most likely cover their short above the IPO price! call it a prophecy! I actually believe that they created an opportunity for people to invest below its fair value(just like Warren Buffet). SMileDirect is building is brand and a moat for it lost

cost service and product that helps people, what matters in the short run is revenue growth. \$2 target? why not \$0 target if you believe it's such a bad company! They have minimal amount of debt and exponential revenue growth.

Reply (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/?replytocom=33129#respond>)

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**george georgaklis** (<http://drgeorgedds.com>) says:

October 7, 2019 at 7:12 pm (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/#comment-32865>)

i spoke with Therese.

Keep me posted!

Reply (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/?replytocom=32865#respond>)

Pingback: The Sniff Test: Just one day after a short seller slammed SmileDirectClub, all 10 banks on its IPO rate it a buy – Buzzmark News (<https://www.buzzmarknews.com/the-sniff-test-just-one-day-after-a-short-seller-slammed-smiledirectclub-all-10-banks-on-its-ipo-rate-it-a-buy/>).



**Longdong Grosserschwanz** says:

October 8, 2019 at 4:26 pm (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/#comment-32871>)

This report is actually a good one, and it doesn't even get into the issue of the TAM math, which argues for growth hitting a wall much sooner than they are guiding analysts. If the TAM is 20 million people, and it replenishes somewhat each year, then it is actually very hard to exceed 1.0 million case starts per year for an extended period of time. If you look at the adoption rates of other consumer discretionary services, stuff like Botox, among others, you'd see that they usually penetrate only a few points of the market per year. It makes sense. You have crooked teeth, you want them fixed... the people who really care about their appearance will act sooner, but once the "early adopters" have signed up, then you get into the people who think "yeah I want to do this... at some point... maybe next year... maybe I'll do a vacation first... maybe I should save a little more... let me revisit this next year." It's just the way large ticket consumer discretionary products tend to see adoption. And those were products without competition.

Thus, for Smile Direct to achieve the targets they are hinting at by the middle 2020's (well over 2 million case starts), they would have to follow a much, much steeper adoption curve than we usually see. Or they will need to have runaway success in overseas markets.

It's an aggressively managed company, with aggressive street expectations. The fact they pushed so hard on maximizing IPO pricing suggests they knew this thing was a house of cards, and they just wanted to be able to monetize as much in the IPO as they could, with no regard for building trust or goodwill. If this were a durable franchise, consistently compounding value, they would have been less greedy, so as to not burn bridges in advance of a large number of looming secondaries.

What goes around cumms around, especially my longdong!! – LG

Reply (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/?replytocom=32871#respond>)



**David** says:

October 10, 2019 at 9:35 pm (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/#comment-32887>)

Nice work

Reply (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/?replytocom=32887#respond>)



**Will not say due to the litigious nature of SDC** says:

October 12, 2019 at 5:04 pm (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/#comment-32904>)

Very well researched and prepared article that needs to "get out there." I will be sharing it. Read the BBB complaints—they all sound similar/the same (all 1270 of them). Go to SDC Facebook page and feel for the poor customers on there asking when their aligners are really going to show up and how they can cancel (good luck with that)...and read the canned responses from SDC. Someone I know who dealt with them was appalled at the consent form the company made her sign in order to get her refund (she had no aligners yet had to beg for her money back and sign a document she did not agree with): she was to delete any negative reviews, retract any official complaints with agencies, and keep anyone else from seeing the consent form! What kind of business demands this after they have failed to supply the service that was paid for? I can't imagine they will be around for much longer, but God help the people who pay these people because they feel they can't afford real treatments.

Reply (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/?replytocom=32904#respond>)

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[\(http://www.jamesonresearch.net/2019/11/13/the-ratings-game-smiledirectclub-stock-slides-another-18-as-investor-sentiment-remains-at-odds-with-bullish-analyst-notes/\)](http://www.jamesonresearch.net/2019/11/13/the-ratings-game-smiledirectclub-stock-slides-another-18-as-investor-sentiment-remains-at-odds-with-bullish-analyst-notes/)

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(<http://www.dailymarket411.com/2019/11/13/the-ratings-game-smiledirectclub-stock-slides-another-18-as-investor-sentiment-remains-at-odds-with-bullish-analyst-notes/>)

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**manley roe** says:

November 14, 2019 at 9:44 am (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/#comment-33087>)

short seller or not you should do a public service and send a copy of this tretis to every dental state board in the country.the problems associated with this treatment are unfathomable to the general public and are difficult to fix inexpensively or quickly.

Reply (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/?replytocom=33087#respond>)



**Ellie Kesselman** (<https://myindigolives.wordpress.com>) says:

November 24, 2019 at 11:52 am (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/#comment-33143>)

Hi Nathan! I didn't realize you left ClaritySpring until today.

You did excellent work here! MarketWatch wrote up some excellent coverage of your findings on SmileClub Direct. I went ahead and updated your Crunchbase start-up profile, created a new entry for Hindenburg Research as a company with you as the founder. I also posted the MarketWatch news story associated with this post, as press coverage. If you have any others you want me to add, I can.

Forensic financial research is very satisfying. I miss doing due diligence for Standard & Poor's, before CBO/CLOs et al. Don't be a stranger. I am proud of the good job you are doing to make investors AND the general public safer.

Reply (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/?replytocom=33143#respond>)

Pingback: Inside the battle between Smile Direct Club and 'organized dentistry' | Real Barholle  
(<https://shaughnbarholle.com/inside-the-battle-between-smile-direct-club-and-organized-dentistry/>).

 **Sickened** says:

December 13, 2019 at 7:14 pm (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/#comment-33284>)

You are seriously making fun of people who don't have the money you have? This company is taking advantage of just that. Shame on you and them. Soulless.

Reply (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/?replytocom=33284#respond>)

 **Don Woodworth DDS MSD** says:

January 11, 2020 at 3:21 pm (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/#comment-33508>)

Great research report! After 37 years in the practice of orthodontics I have seen many problems. General dentists do Invisalign and get themselves into situations they cannot get out of. Eventually they send the patient over to me and I try to work out of the issues without placing braces. Many times bite problems occur making things difficult. I cannot imagine treating a patient without seeing them. Time to buy puts.

Reply (<https://hindenburesearch.com/smiledirectclub-moving-fast-and-breaking-things-in-peoples-mouths/?replytocom=33508#respond>)

Pingback: Debunking the claims of SDC  
(<http://madrasdentalcare.com/index.php/2020/01/31/debunking-the-claims-of-sdc/>).

Pingback: SmileDirectClub stock slides 15% as it hits back at NBC report that it harms consumers - Investing Chatter (<https://www.investingchatter.com/smiledirectclub-stock-slides-15-as-it-hits-back-at-nbc-report-that-it-harms-consumers/>).

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Theme by Robert DeVore (<https://robertdevore.com>).

# Exhibit 12



May 10, 2019

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061, HRA-305  
Rockville, MD 20852

Re: Docket FDA-2019-P-2038: SmileDirectClub, LLC Comment to the Citizen Petition Filed by the American Dental Association

To Whom It May Concern:

SmileDirectClub, LLC (“SDC” or the “Company”) is submitting this comment to the Citizen Petition filed by the American Dental Association (“ADA”) under docket number FDA-2019-P-2038 to correct several misleading statements and inaccurate information contained in the ADA’s Citizen Petition. The descriptions in the Citizen Petition of SDC’s business and the prescribing practices of the state-licensed dentists and orthodontists (collectively, “doctors”) who engage SDC for its administrative, non-clinical dental support organization services (“DSO Services”) are almost entirely incorrect. The Citizen Petition (1) misrepresents the prescription process for the aligners and impression kits sourced by SDC for its affiliated doctors; (2) misunderstands the Company’s FDA establishment registration and device listing obligations; and (3) raises practice of dentistry concerns that are not appropriate grounds for a citizen petition submitted to FDA. This comment addresses each aspect of the Citizen Petition in turn.

First, contrary to what the petition would have FDA believe, all sequential aligners (“aligners”) prescribed by the doctors who utilize SDC’s DSO Services, are sourced by SDC from FDA-registered manufacturing facilities that are also MDSAP- and ISO-certified. Further, SDC only provides its DSO Services to doctors who are in good standing with the dental boards in the states where they are licensed to practice, who have at least four years of experience in treating their patients with clear aligner therapy, and who have received a certificate from Invisalign on clear aligner therapy training. In addition, as with any traditional doctor-DSO arrangement, the doctors who contract with SDC are solely responsible for all clinical aspects of their patients’ evaluation, diagnosis, prescription, and treatment. Regarding the misstatements and inaccurate information set forth in the Petition regarding the impression kits, all impression kits containing dental impression material are dispensed not by SDC but by an affiliated dental laboratory and are only dispensed pursuant to a valid prescription from a doctor who is licensed in the patient’s state of residence who has requested the impression kit. Second, as FDA knows, SDC has complied fully with FDA’s establishment registration and device listing requirements. The Agency reviewed and evaluated SDC’s registration and listing filings as recently as last month and is aware of the Company’s practices and operations. Third, because FDA does not regulate the practice of



medicine or dentistry, the ADA's complaints regarding the standard of care for the practice of dentistry—complaints which form the bulk of the Citizen Petition—are not appropriate grounds for a citizen petition to FDA. The regulation of the standard of care in the practice of dentistry falls under the purview of the individual state dental boards, and SDC's operations as a DSO—and those of its affiliated doctors—are structured to ensure compliance with all state requirements regarding the practice of dentistry.

SDC has enabled the doctors who use its DSO Services to help over 500,000 patients receive access to high-quality dental care. Of course, SDC and its affiliated doctors are always disappointed to hear about the few patients who are unhappy with their outcomes, including those patients whose experiences are cited in the Citizen Petition, but such unanticipated results are an infrequent and unfortunate outcome of all medical and, more specifically, dental care, whether it is provided via teledentistry or in a more traditional brick and mortar dental practice. SDC and the doctors who use its DSO Services are confident that SDC's novel teledentistry platform enables these doctors to provide aligners with good outcomes and a low risk profile for the overwhelming majority of patients, many of whom would otherwise not have access to this type of treatment. See Attachment 1 for just a few examples. The Company is also confident in the structure of its operations and its affiliated doctors' compliance with applicable standards of care, as described in this comment.

### **Brief Description of SDC's Teledentistry Platform**

SDC is a dental services organization ("DSO") that provides administrative, non-clinical support services ("DSO Services") for doctors and their professional corporations. These DSO Services include, but are not limited to, the use of SDC's proprietary teledentistry platform ("SDC Teledentistry Platform"). On behalf of the doctors, SDC also sources from an affiliated dental lab dental impression material (provided in dental impression kits, except when the kits were sold at retail as New Smile Kits, as described below) prescribed by the doctors and sources the customized clear aligners prescribed by the doctors from either Align Technology, Inc. or an SDC-affiliated manufacturing facility.

Using the SDC Teledentistry Platform, the doctors review and evaluate patients' medical and dental history, dental photographs, and a 3-D dental image of the patient's teeth and gums, as well as such other information that the doctor may request. As with any other DSO model, the decision whether to proceed with aligner therapy for a given patient is in the sole discretion of the doctor; SDC has no part in any clinical or patient care decisions. Using the SDC Teledentistry Platform, the doctors can: determine whether to approve a patient's treatment plan and authorize the patient for treatment; determine that the patient is not an appropriate candidate for treatment; request additional information, such as radiographs or periodontal clearance before making a determination as to treatment; or seek revisions to the treatment plan. Although SDC makes its SDC Teledentistry Platform available to the many doctors who choose to use it, neither the doctors nor the professional corporations with which they are affiliated are obligated to use the SDC Teledentistry Platform, to prescribe the clear aligner therapy, or to source the clear aligners through SDC.

If a doctor authorizes a patient for clear aligner treatment and wishes to have the aligners sourced through SDC, the doctor then issues an individual prescription for the patient's customized clear

aligners. SDC sources the customized aligners for manufacturing by an FDA-registered manufacturer, pursuant to the prescription and a valid 510(k) clearance, on behalf of the doctor.

**SDC Provides Impression Kits and Aligners Pursuant to Valid Prescriptions Written by Licensed Dentists and Orthodontists**

The Citizen Petition alleges that SDC sells aligners and impression material in an over-the-counter manner, without a valid prescription. This is simply untrue. As described above, SDC only sources the manufacturing and dispensing of the impression material and aligners pursuant to a valid prescription written by a doctor who is licensed by the board of dentistry in the patient's state of residence.

Specifically, the aligners are only manufactured and shipped after the manufacturing facility engaged by SDC receives a prescription for an individual patient from a doctor, which prescription is written only after the doctor evaluates the patient's individualized draft treatment plan, medical and dental history, dental photographs, 3-D dental image, and such other information that the doctor believes is necessary or desirable for that particular patient.

Further, impression material is dispensed by a dental laboratory pursuant to a prescription from a doctor and only to potential patients that have requested the same and have registered their information using the SDC Teledentistry Platform. The dental lab ships the impression material pursuant to this valid prescription. SDC requires that the prescription be from a doctor that is licensed in the potential patient's state of residence.

Finally, the Citizen Petition references SDC's "New Smile Kits," which were previously sold in retail stores. SDC wants to stress that (a) such kits are no longer sold in retail stores and (b) at no time did the New Smile Kits contain impression material or any other prescription medical device, a key fact that the Citizen Petition fails to disclose. Instead, the impression material was dispensed by the dental lab referred to above only if the purchaser of a New Smile Kit had registered the kit and their information using the SDC Teledentistry Platform and only pursuant to a prescription from a doctor licensed in the patient's state of residence.

**SDC Complies with FDA Requirements for Establishment Registration and Device Listing and Manufacturing under a Valid 510(k) Clearance**

The Citizen Petition also alleges that SDC has not properly registered its facility with FDA and is not manufacturing aligners pursuant to a valid 510(k) clearance. This is also untrue. The ADA's allegations appear to stem, in part, from the belief that SDC provides aligners on behalf of doctors in an over-the-counter manner. As explained above, that is incorrect; the manufacturers of the aligners that SDC procures on behalf of the doctors who contract with SDC for DSO Services ship aligners only pursuant to valid prescriptions from the doctors and manufacture them pursuant to a valid 510(k) clearance. The ADA's allegations also appear to be based on outdated (and wholly misunderstood) information about SDC and its affiliates' operations.

SDC contracts with manufacturing facilities to produce aligners when prescribed by the doctors who contract with SDC for DSO services. Each of those manufacturing facilities is appropriately registered with FDA, and all of the aligners are manufactured pursuant to valid, FDA-cleared 510(k) clearances. These facilities are also MDSAP- and ISO-certified. Because SDC does not

perform any manufacturing, contract manufacturing, repackaging, or relabeling activities in its role as a DSO, SDC deactivated its establishment registration with FDA.

Finally, SDC wants to clarify that neither SDC nor its affiliates are repackagers or relabelers of the dental impression material dispensed to patients in impression kits (again, dispensed only after patient registration using the SDC Teledentistry Platform and pursuant to a valid prescription from a doctor licensed in the patient's state of residence). SDC's affiliated dental lab provides impression material to patients in its capacity as a dental laboratory. Importantly, FDA does not regulate dental laboratories and does not require them to register their facilities with the Agency. *See* 21 C.F.R. § 807.65 ("The following classes of persons are exempt from registration . . . (i) [p]ersons who dispense devices to the ultimate consumer . . . for example, a . . . dental laboratory . . . whose primary responsibility to the ultimate consumer is to dispense or provide a service through the use of a previously manufactured device.").

### **FDA Does Not Regulate the Practice of Dentistry**

The ADA is undoubtedly well aware that FDA does not regulate the practice of medicine or dentistry by licensed healthcare professionals, including dentists and orthodontists, nor does the Agency regulate dental laboratories that dispense medical devices to patients. Despite this fact, the bulk of the complaints in the Citizen Petition relate to the ADA's misconstrued perception of the dentistry practiced by doctors who contract with SDC for DSO Services, including the SDC Teledentistry Platform. Specifically, the ADA devotes many pages to explaining the ADA's opinion that these doctors' form of dentistry does not fit the ADA's notion of the standard of care for teledentistry. The proper forum for such complaints is not an FDA Citizen Petition, but the various state boards of dentistry. In fact, the American Association of Orthodontists ("AAO"), whose interests often align with those of the ADA, filed complaints similar to the Citizen Petition in 36 states in 2017, and yet, none of the states have taken action against SDC or its affiliated doctors, and 14 of these state dental boards have officially closed their investigations.

Indeed, the federal Food, Drug, and Cosmetic Act ("FDCA") is clear that FDA does not regulate the practice of medicine (or, by extension, the practice of dentistry):

Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.

21 U.S.C. § 396. The ADA's arguments regarding the supposed failure of the doctors who contract with SDC for DSO Services to conform to the ADA's standards for the practice of teledentistry are therefore not appropriate grounds for a citizen petition submitted to FDA.

Despite the fact that a Citizen Petition submitted to the FDA is not the proper manner for assessing the current standards of the practice of dentistry, SDC wishes to correct the misinformation in the ADA's Citizen Petition regarding the practice of teledentistry by the doctors who contract with SDC for DSO Services, including the SDC Teledentistry Platform. The Citizen Petition alleges that SDC's business model has "virtually eliminated substantive participation by a dentist." As described above, this statement is blatantly incorrect. All aspects of the patients' clinical care,

from start to finish, as with any other DSO model, are solely the responsibility of the doctors, regardless of whether the doctors use the SDC Teledentistry Platform to provide their patients with clear aligner therapy. Final decisions regarding the patient's treatment plan and the ultimate decision as to whether a patient is an appropriate candidate for aligner treatment are made solely by these doctors following their review of the patient's 3-D digital image, photographs, medical/dental history, chief complaint, proposed treatment plan, and such other information that doctor deems necessary, in accordance with accepted dentistry practices. The doctor has the authority and discretion to request additional information, such as radiographs or periodontal clearance, before making a determination as to treatment. Further, throughout the treatment period, the doctor is solely responsible for monitoring his or her patient's treatment until completion, with check-ins as often as the doctor chooses but occurring every 90 days, at a minimum. At any time during treatment, the doctor also has the authority and discretion to request or require additional information, an in-person office visit, or a mid-course correction.

In addition, the Citizen Petition takes issue with statements made by SDC that the process used by the doctors that contract with SDC for DSO Services, and their use of the SDC Teledentistry Platform, meets the appropriate standard of care. Although the ADA may think that the process used by these doctors, as expressed by the ADA in an incomplete and inaccurate manner, is not consistent with the ADA teledentistry standards, the doctors who have contracted with SDC for DSO Services, and who use the SDC Teledentistry Platform, do follow accepted teledentistry practices as set forth by the American Teledentistry Association ("ATDA"). There may be disagreement between the ADA and ATDA regarding what constitutes the proper standard of care in today's modern age, but that is not a dispute for FDA to resolve.

\* \* \* \* \*

SDC encourages FDA to deny, in full, the ADA's Citizen Petition, which presents an inaccurate and misleading picture of SDC's DSO Services and the SDC Teledentistry Platform. Contrary to the ADA's misstatements, each patient's aligners are provided pursuant to a valid prescription written by a doctor licensed to practice dentistry in the patient's state of residence. Further, SDC's affiliated dental lab dispenses impression material to patients pursuant to valid prescriptions issued by a doctor licensed in the patient's state; New Smile Kits previously sold in retail stores did not contain impression material. Neither SDC nor its affiliates provide aligners or impression material on an over-the-counter basis. In addition, the registration status of SDC and the manufacturers from which it sources patient-customized aligners is proper and current. Finally, SDC is confident that its operations, and those of the doctors who contract with SDC for DSO Services and the SDC Teledentistry Platform, are consistent with the valid and appropriate practices of teledentistry and dentistry pursuant to the state laws that regulate such practices. Although the ADA may disagree about that, FDA does not regulate the practice of dentistry, and thus the ADA's complaints on that topic are not appropriate grounds for a Citizen Petition.

Doctors utilizing SDC's Teledentistry Platform have helped bring access to orthodontic care to urban and rural areas across the country, reaching many people who otherwise would be unable to

afford treatment. The ADA's opinion on the standard of care, as expressed through its Citizen Petition, should not be permitted to preclude or limit patients' and doctors' options for safe and effective orthodontic treatment.

If you have any questions about this comment, SDC's operations, or the medical devices that it sources from manufacturers at the request of the doctors who contract with SDC for DSO Services, please let us know. We look forward to speaking with you.

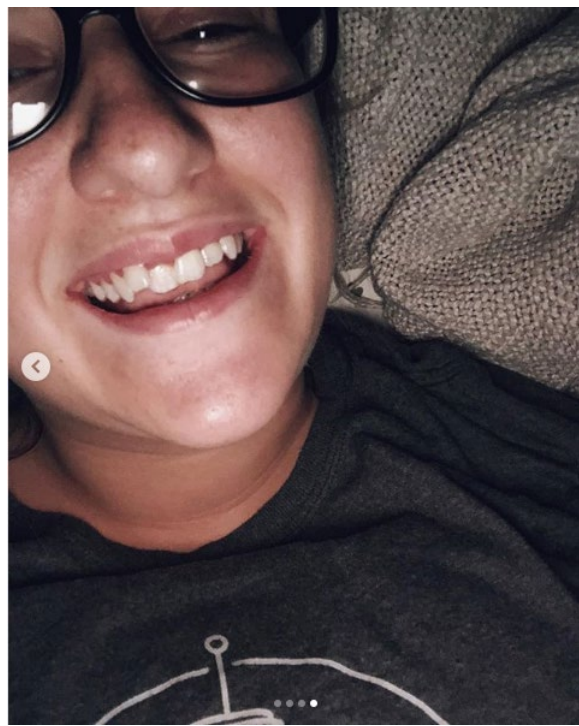
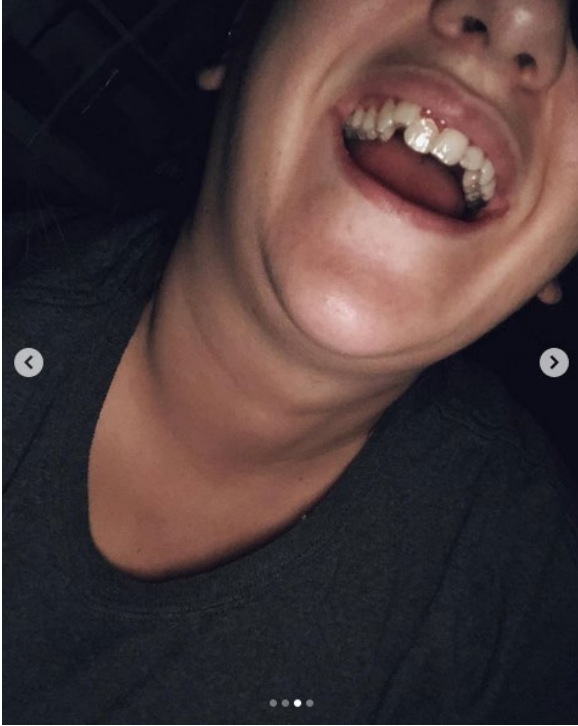
Sincerely,

A handwritten signature in blue ink that reads "Jeffrey Sulitzer, DMD". The signature is written in a cursive style.

Jeffrey Sulitzer, DMD  
Chief Clinical Officer

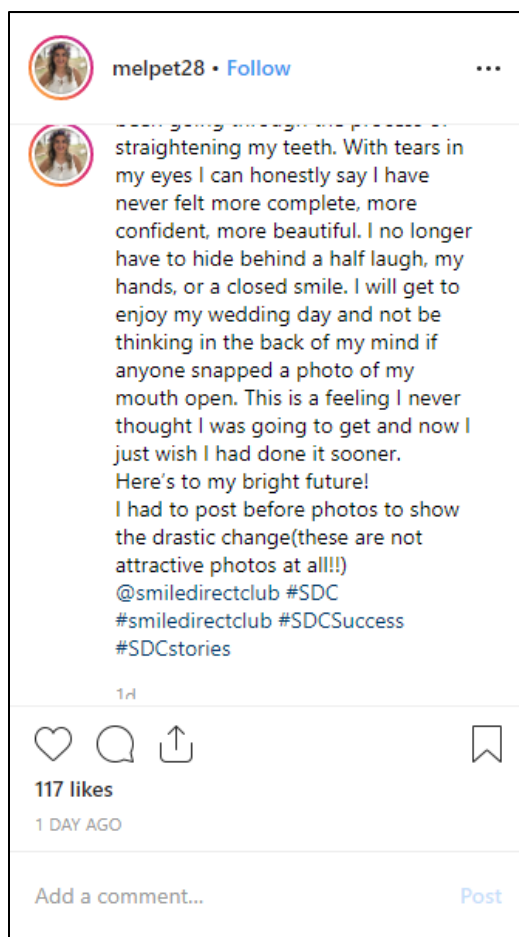
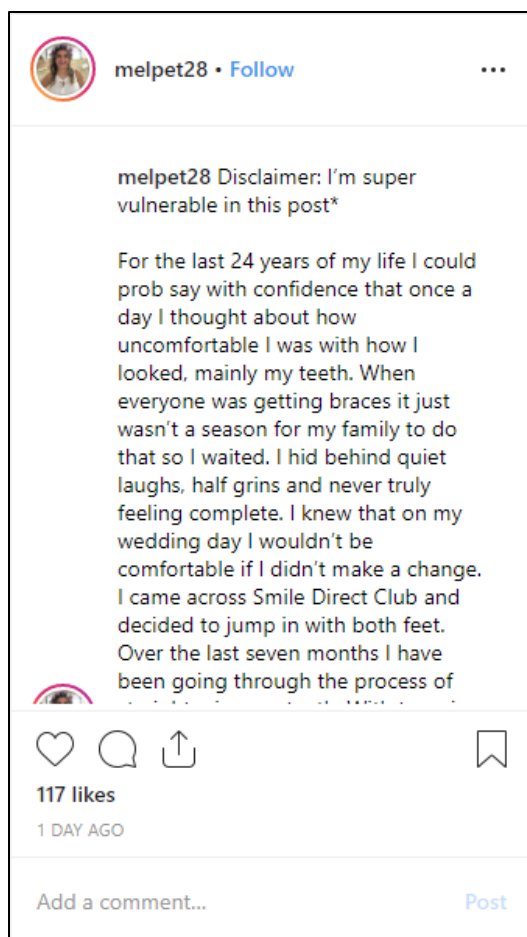
# Attachment 1





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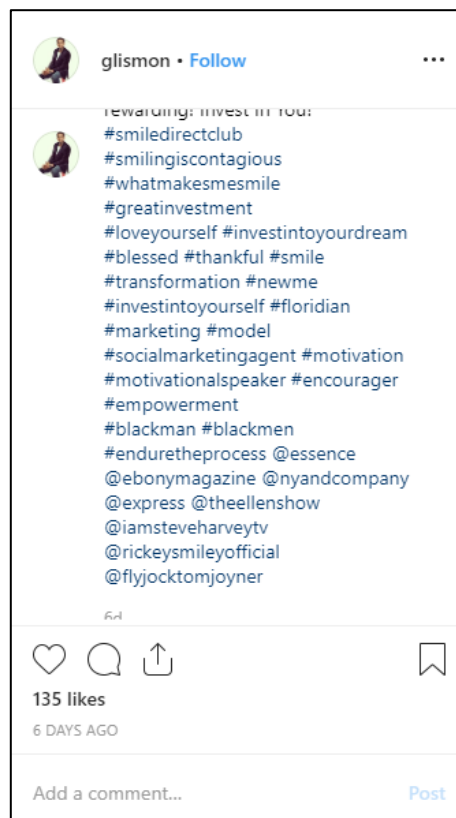


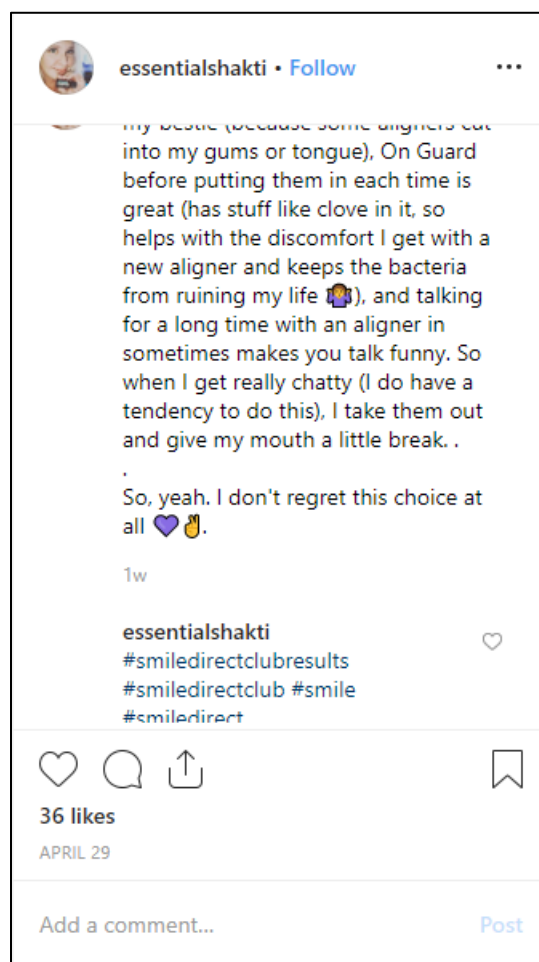
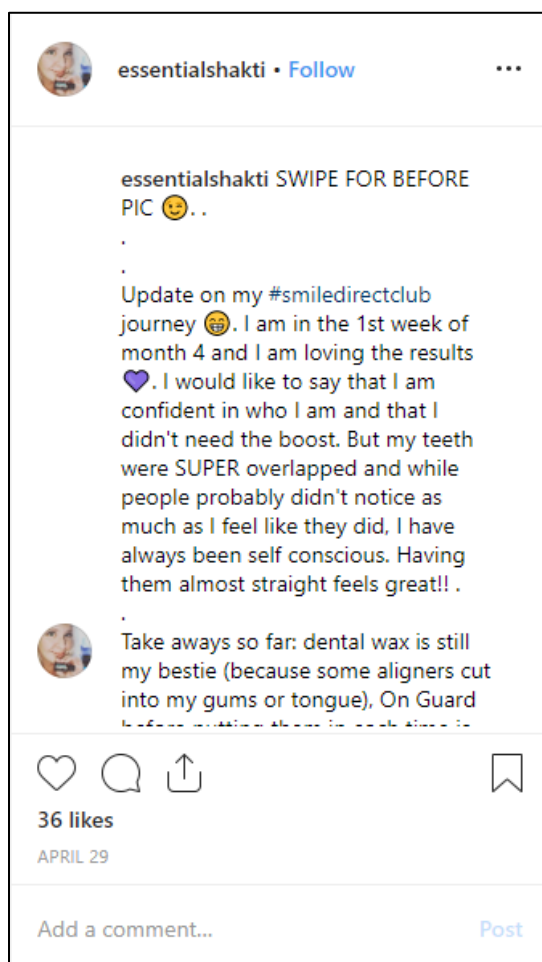
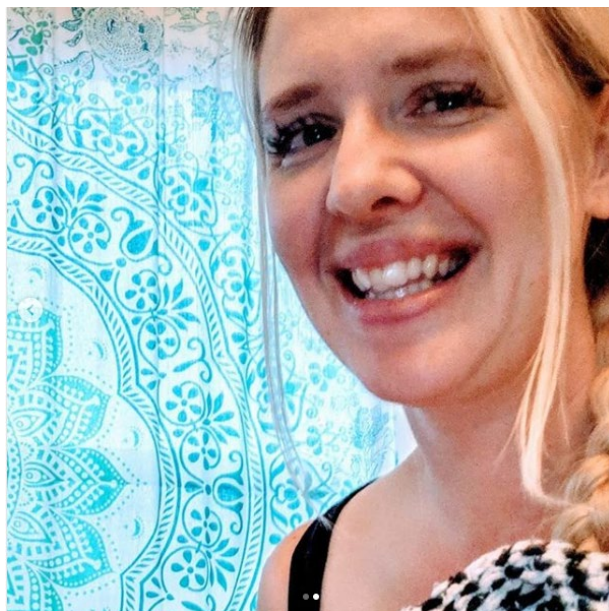


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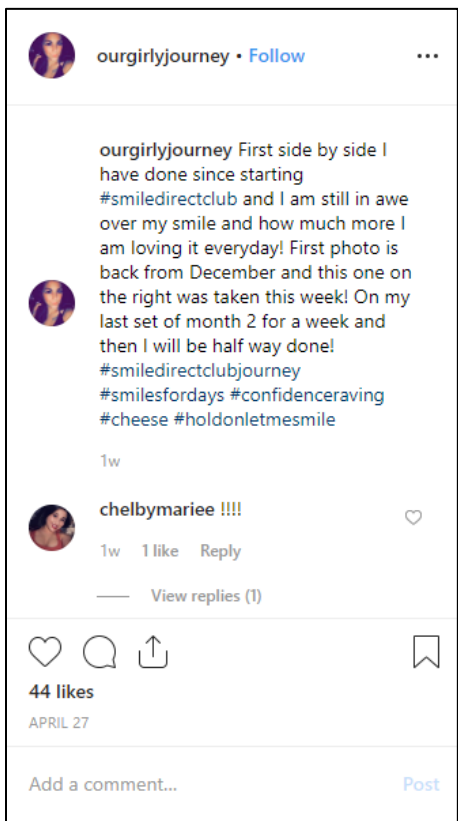
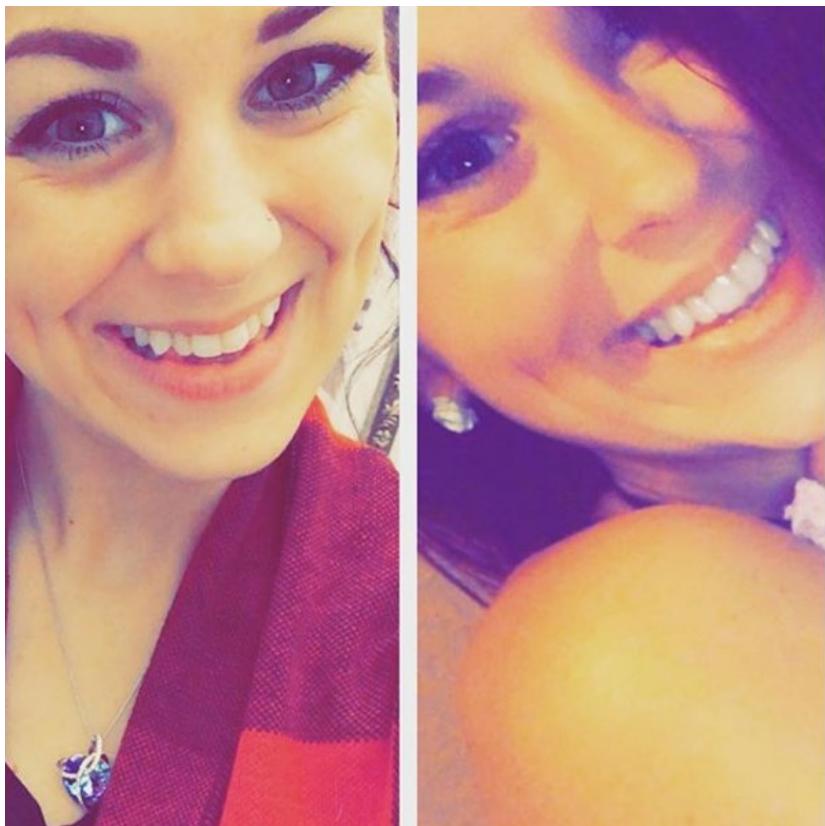


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**rebeccaheinnell** • Follow  
Fort mcmurray, alberta

rebeccaheinnell Neither of these are flattering photos of me but I thought it was about time I shared a little comparison of my teeth before @smiledirectclub and my progress so far... Back in high school I had braces and they gave me the smile I had always wanted. In recent years since my wisdom teeth came down my teeth had shifted not back to their original position before braces but far from what I had achieved with braces. I began smiling with my mouth closed... covering my mouth when I laughed... and just being all around negative about my smile. I'm about half way through my treatment yet and the results have been incredible so far. I cant wait for






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the finished product. I'm so much more confident in my smile all ready. If you are on the fence or have been thinking about trying SmileDirectClub I highly encourage you to go ahead and try it!!! You can even message me for a promo code that will get you a discount on your invisible aligners. I can honestly say - the first few days were quite painful as my mouth got used to the aligners but once you power through that the discomfort is so mild. I like to change my aligners before bed and wake up with that pressure from the new set gone!

Dont hesitate to message me if you have any questions :)

3w





311 likes

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[https://www.instagram.com/p/BwZrnY\\_A8j8/](https://www.instagram.com/p/BwZrnY_A8j8/)

# Exhibit 13



# North Dakota State Board of Dental Examiners

Administrative Office • P.O. Box 7246, Bismarck, ND 58507-7246 • 701-258-8600 • Fax 701-224-9824 • info@nddentalboard.org • http://www.nddentalboard.org

**EXHIBIT "A"**

**Minutes  
SPECIAL MEETING  
April 14, 2022 | 5:30 PM CDT  
Via Zoom Meeting**

- 1. Call to Order and roll call:** The North Dakota Board of Dental Examiners convened for the purpose of discussion of written and oral comments regarding amendments to Title 20 of the North Dakota Administrative Code. Board President, Tim Mehlhoff called the virtual meeting to order at 5:30 PM CDT.

**Board Members and Administrative Staff Attendance**

Tim Mehlhoff, CPA	Bev Marsh, RDH President -Elect
Otto Dohm, DDS, MS	Andrea Carlson, RDA
Marcus Tanabe, DDS, OMFS, Secretary Treasurer	Allison Fallgatter, DDS
Joel Kangas, DDS	Rita Sommers, RDH, MBA, Executive Director
David Schaibley, Assistant Attorney General	Absent: Michael Keim, DDS

Other known members of the public in attendance: Bobbie Will, Community HealthCare Association of the Dakotas; Will Sherwin, Esq. North Dakota Dental Association (NDDA); Cari Orn, DDS, NDDA; Marsha Krumm, RDA, North Dakota Dental Assistants' Association (NDDAA); Katherine Landsberg, Dental Assisting National Board (DANB); Sasha Dusek, RDA, NDDAA; Trey Lawrence, Esq., American Association of Orthodontists (AAO); Jeffrey Sulitzer, DDS, SDC; Justin Hagel, Marc Ackerman, DMD, American Teledentistry Association; Levi Andrist, Esq. SDC

- 2. Complaint Committee:** At the Board's March 8, 2022 meeting a motion was made regarding Robert Bates, DDS, which mistakenly did not reflected the Board's intent. Dr. Dohm moved to retract the motion made regarding complaint number 49-0211 at the March 8 meeting and further moved to retroactively suspend the license of Dr. Bates for violation of NDCC § 43-28-18(1),(29). Motion seconded by Ms Carlson. Roll call vote: Mr. Mehlhoff, yes; Dr. Kangas, yes; Ms. Marsh, yes; Dr. Dohm, yes; Dr. Fallgatter, yes; Ms. Carlson, yes; Dr. Tanabe, yes. Motion carried 7-0.
- 3. The Board allowed additional commentary** for those entities joining the meeting and requesting additional discussion.

NDAC SECTION ADDRESSED AND/OR CONCERN	COMMENTATOR	SUMMARY OF COMMENT
Definitions: 20-01-02-1(38) [38. "Qualified dental assistant" means a dental assistant who has been employed and trained as a dental assistant and has received at least <del>six</del> <u>three</u> hundred <del>fifty</del> hours of on the	Katherine Landsberg	Ms. Landsberg provided clarity regarding eligibility requirements of DANB's NELDA exam. DANB supports the on-the-job training hours required for the Qualified Dental Assistant in conjunction with the NELDA examination process and eligibility requirements.



<p>job training, and <u>successfully completed a board approved infection control seminar and passed the x-ray, infection control, and dental anatomy</u> portions of the dental assisting national board examination and has applied to the board and paid the certificate fee and met any other requirements of section 20-03-01-05.]</p>		
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**BOARD RESPONSE TO ORAL COMMENT:** The Board appreciates the comment, and the suggestion was adopted by the Board. The Board seeks to provide additional pathways for dental assistants to enter the workforce and therefore added the language, or a board approved equivalent course as seen below creating a 4<sup>th</sup> pathway for dental assistants entering the dental job market. Amended no. 38 was further amended as shown in highlighted text to:

38. "Qualified dental assistant" means a dental assistant who has been employed and trained as a dental assistant and has received at least ~~six~~ three hundred ~~fifty~~ hours of on the job training, and successfully completed a board approved infection control seminar and passed the national entry level dental assistant certification administered by x-ray, infection control, and dental anatomy portions of the dental assisting national board examination, or other board approved course, and has applied to the board and paid the certificate fee and met any other requirements of section 20-03-01-05.]

Ms. Marsh commented on deleting the 300 hours from pathway #3 because of the requirements of the ND Dept of Career Technical Educations layer of requirements for the program. The Board also deleted language related to the ND institution to safeguard those students who may take the education out of state.

2. The board may grant registration as a qualified dental assistant to an applicant meeting all the following requirements:

a. The applicant meets any of the following requirements:

- (1) The applicant passed the ~~infection control and radiation parts of~~ national entry level dental assistant certification administered by the dental assisting national board examination and completed 300 hours of on-the-job clinical training within one year of application.
- (2) The applicant passed the ~~infection control and radiation parts of~~ national entry level dental assistant certification administered by the dental assisting national board examination, 300 hours of on-the-job clinical training, and completed within two years before application, sixteen hours of continuing education in accordance with section 20-03-01-06.
- (3) The applicant successfully completed the national entry level dental assistant certification administered by the dental assisting national board and successfully completed the North Dakota State Department of Career Technical Education dental assisting education program association or board approved equivalent course offered by a North Dakota institution of higher education and submits evidence of 300 hours of on-the-job clinical training within one year of application.
- (4) The applicant completes a board approved equivalent course within one year of application.



NDAC SECTION ADDRESSED AND/OR CONCERN	COMMENTATOR	SUMMARY OF COMMENT
<p>1<sup>st</sup> concern: 20-03-01-01(1.k.)  <u>[Take dental photographs including the use of intraoral cameras on a patient of record.]</u></p> <p>2<sup>nd</sup> concern: 20-02-01-09 (2.j.)  <u>[Each patient shall have access to health provider info as it pertains to their treating doctor or potential doctor. Any entity, utilizing telehealth must provide upon request of a patient the name of the dentist, telephone number, practice address, and state license number of any dentist who was involved with the provision of services to a patient before, prior to or during the rendering of dental services. ]</u></p>	<p>Marc Ackerman, DMD, American Teledentistry Association</p>	<p>Concern with issue of the taking of photographs and new technology, handheld advanced digital cameras, e.g. camera phones. A dental assistant under direct supervision is a barrier to the use of “teledental care” and suggested the need of the population is for an increase in dental care in rural and urban on demand local dentists. He feels the need is not being met and that teledentistry is the best option. “It’s our feeling that taking photographs is not the practice of dentistry” Dr. Ackerman opined, that intraoral digital scans are the same as simple photographs and that this rule states that it is the practice of dentistry and “since the photograph is taken under direct supervision, the doctor is involved.”</p> <p>Also concerned with the Board’s opinion of “what is a bonified doctor-patient relationship” Ackerman commented that all 50 states have determined what a qualified doctor patient relationship is and shared thought’s why the Board’s rules are not in step with telemedicine or telehealth regarding the doctor patient relationship.</p>

#### BOARD RESPONSE TO ORAL COMMENT:

Regarding Dr. Ackerman’s 1<sup>st</sup> concern about (20-03-01-01(1)(k)) “taking dental photographs including the use of intra oral cameras on a patient of record,” A dental assistant authorized to take photographs of existing conditions or utilizing the intra-oral camera has the least amount of training and no formal education in dentistry other than some amount of “on the job” training which is currently not regulated or required. “Once a record-taking process ensues” Ms. Marsh commented, “the patient definitely becomes a patient of record.” A dentist looking at photos or intra oral photos would most likely be reviewing these materials to establish a diagnoses and/or treatment plan. SDC commented that no clinical knowledge is required to gather such elements. However, anyone who is not sufficiently educated could struggle to recognize essential elements when taking intra oral photographs of the mesial buccal aspect of tooth number 30 or other anatomical structures. SDC is only considering the use of the Cerec, iTero or other intraoral scanner use. The issue is also related to whether a final image is being captured for use in treatment itself or to establish a diagnoses where an inadequate images can be problematic. SDC uses the verbiage of scan and photograph as interchangeable, and anyone can do either when in fact a photograph is different than capturing a 3D digital scan.

Regarding Dr. Ackerman’s 2<sup>nd</sup> concern – the doctor patient relationship. Existing North Dakota telehealth statute specifically states a dentist is held to the same standard of care and ethical standards, whether practicing traditional in-person dentistry or telehealth. Before a dentist initially diagnoses or treats a patient, the dentist shall perform the exam or evaluation which can be done through telehealth if the exam or evaluation may be performed in accordance with the standard of care required for an in person dental examination or evaluation. SDC indicated it opposes rules that are less stringent than the actual law regarding telehealth. Existing telehealth laws are actually more stringent than the rules proposed by the Board, ie. 20-02-01-09(2)(j) “Each patient shall have access to health provider information as it pertains to their treating doctor or potential doctors. Any entity, utilizing telehealth must provide upon request of the patient the name of the dentist, telephone number, practice address, and state license number of any dentist who was involved with the provision of services to a patient before, prior to or during the rendering of dental services.” Whereas current telehealth law states “A dentist practicing telehealth shall verify the identity of the patient seeking care and shall disclose to the patient the dentist’s identity, physical location, contact information, and licensure status.” Statute states the information must be provided. The Board does not believe that a phone number requirement is overreaching or a burden to the practitioner utilizing telehealth. Therefore, the Board disagrees with Smile Direct Club and agrees with statute established by the ND Legislature.



Dr. Ackerman also commented on the American Medical Associations position on the doctor-patient relationship related to telehealth and stated the Board's rule is not in step with the current standards when in fact the ND Board of Medicine laws contain exactly the same language (see NDCC 43-17-44(2)).

The Board's language simply validates the statute (NDCC § 43-28-11.3) by referring to the contact information language found in NDCC § 43-28-11.3. The Board feels that a telephone number is one ingredient in "contact information" that should be provided upon request of the patient. Therefore the Board disagrees with Ackerman that any changes should be considered to the amendment, and disagrees that the language is overreaching and submits that it is a patient's right to have knowledge of the information as part of the doctor patient relationship.

NDAC SECTION ADDRESSED AND/OR CONCERNS	COMMENTATOR	SUMMARY OF COMMENT
NDCC 43-28-11.3(2)	Levi Andrist, Esq representing Smile Direct Club	Mr. Andrist stated he wants to hear Boards comments in unison with HB 1151." Concerns were raised with the Board and Mr Andrist felt they were "unaddressed." Smile Direct then worked with the legislature to pass HB 1151 – teledentistry standards because the Board did not address Smile Direct Clubs concerns. "This is third time we have engaged with the Board, and we [SDC] still have some lasting concerns".
20-02-01-09 (2.j.) Each patient shall have access to health provider info as it pertains to their treating Dr. Any entity utilizing telehealth must provide upon request of a patient the name of the dentist, telephone number, practice address, and state license number of any dentist who was involved with the provision of services to a pt. before, prior to or during the rendering of dental services.	Dr. Sulitzer, Chief Clinical Officer of Smile Direct Club	Dr. Sulitzer: Concern 1. Providing address phone number or other contact information would not be a concern for a traditional dental setting and concerned with rules for dentist using teledentistry. The rules or standard should be the same for both. "Just because you go to a brick-and-mortar practice doesn't mean you know who you are seeing". "At smile direct club our patients know who the doctor is and license number and phone is available. Patients can communicate thru face time, chat, 1-800 number and other ways and therefore patients can get to their doctors." "We are fine with the rule if it is across the board for all dentists." Regarding the scanner, "The iTero is very complex but is easy to use, the machine does all the work and decisions are made from that data." Dr. Sulitzer was concerned that dentists who use teledentistry laws are subject to same laws that apply in traditional brick and mortar settings.
20-03-01-01(1.k.) Take dental photographs including the use of intraoral cameras on a patient of record.	3 points:  1.Contact info for telehealth dentists: 20-02-01-09, and  2. scanning shouldn't require NDBDE credentialing  3. taking scan shouldn't require any type of a dentists' supervision.	2. A dental assistant should not need any credentials or dental educational requirements to take a an intra-oral digital scan or extra-oral photo. He indicated it does not take a skilled person to take a photo or scan, although they do capture important landmarks "because the scanners are idiot proof."  3. Simple cameras and taking photos is easy and should not require supervision as it is not a clinical procedure. Dr. Sulitzer commented that anyone can be trained in about 30 – 60 minutes to use the iTero scanner effectively and ultimately it is up to the doctor to determine if the scan would need to be redone.  4. Definition of a patient record. "Having a patient be a patient of record is a problem".  "We are about access to care at a reasonable cost." Does not believe the rules comply with the statute.



**BOARD RESPONSE TO ORAL COMMENTS:** With regard to 20-03-01-01(1)(k):

To Dr. Sulitzer's points: The question becomes what should the qualifications of the individual taking the final scan that will be used for fabrication of an intraoral device/appliance consist of? Although the doctor ultimately has the final say on the use of the final image/scan, there are other aspects of even the simplest treatment such as considering the patient. If the patient has the digital scan made and the dentist is not readily available to review it, the patient may be significantly inconvenienced because they must return for another scan. Dr. Sulitzer is suggesting any staff member should be allowed to be trained to take the scan with or without the dentist present. The NDBDE felt the importance of the data being acquired and the purpose for which it would be used (diagnosis, treatment planning and/or oral device fabrication) considered the patient who may have taken time away from work, needed to travel or arrange childcare, etc., for a dental appointment. This would be true whether in either traditional or telehealth settings. Mr. Mehlhoff also commented from the consumers point of view; there are also concerns of education and training for infection control issues and other regulations and, therefore, an individual scanning the teeth would require training beyond merely learning to use the scanning device. There is an expectation that the person who takes care of you in the clinical office space where dental treatment is performed, has some level of knowledge, training and proficiency. The Qualified Dental Assistant is required to have infection control continuing education. The dental assistant with no requirements of education or training that provides limited duties is not required to have infection control education. Ms. Marsh commented that the technology is easy to use but believes the language should be left as is and a Qualified Dental Assistant should be able to take the 3D scan (under appropriate supervision) - rather than office personnel such as a receptionist suggested by SDC.

The Board addressed the concerns Regarding Sulitzer's points related to 20-02-01-09 (2)(j) in their response to Dr. Ackerman.

NDAC SECTION ADDRESSED AND/OR CONCERN	COMMENTATOR	SUMMARY OF COMMENT
<p>20-02-01-09 (2)(j)</p> <p><u>Each patient shall have access to health provider info as it pertains to their treating Dr. Any entity utilizing telehealth must provide upon request of a patient the name of the dentist, telephone number, practice address, and state license number of any dentist who was involved with the provision of services to a pt. before, prior to or during the rendering of dental services.</u></p> <p>20-03-01-01(1)(k) <u>Take dental photographs including the use of intraoral cameras on a patient of record.</u></p>	<p>Tray Lawrence, Esq., AAO</p>	<p>Mr. Lawrence Strongly supported providing contact information and identity of the doctor as well as strong support for the necessity that photographs and digital scans be performed by individuals under the supervision of the doctor. "We support access to care which provides patients basic rights, one of which is to be able to contact your doctor to have a conversation via phone or live interaction". "Opponents say they provide this, but why oppose it unless you are NOT in compliance?" There should be no opposition to a rule protecting patients' rights. "The opposition makes a flippant comparison of photos referred to as selfies and how easy it is to take them. The digital scan or iTero scan is NOT just a photo, but technology which replaces the final impression used for treatment and diagnosis". The opponents try to undersell the importance of that first impression used to have a lab make a device. The iTero scanner is very complicated and serves a very important purpose and the complexity is not that of a mere "selfie".</p>

**BOARD RESPONSE TO ORAL COMMENTS:** Based on Mr. Lawrences concerns and others the Board did make changes to sections 20-02-01-09 (2)(j) and 20-03-01-01(1)(k) and feel the changes were consistent with Mr. Lawrences concerns and the Board addressed them in the best way possible.



NDAC SECTION ADDRESSED AND/OR CONCERN	COMMENTATOR	SUMMARY OF COMMENT
20-02-01-05	ADA'S Cathy Baumann, Director NCRDSCB.	The NCRDSCB (National Commission on Recognition of Dental Specialties and Certifying Boards) determined that the requirements for dental specialists had been met and adopted a resolution recognizing the American Board of Orofacial Pain as the national certifying board for orofacial pain.
<b>BOARD RESPONSE TO COMMENT:</b> The Board appreciates the comment; however the information is not directly related to the proposed rules the Board is adopting at this time and the since the comment does not indicate any concerns regarding the proposed rules, the Board will not be making any changes based on this comment.		
NDAC SECTION ADDRESSED AND/OR CONCERN	COMMENTATOR	SUMMARY OF COMMENT
<p>20-01-02-01(39); 20-01-02-01 In support of definition (39) and 20-02-01-05(f) <u>f. The dentist authorized to provide deep sedation and general anesthesia shall utilize and have present a staff of supervised personnel capable of handling procedures, complications, and emergency incidents, including at least two qualified dental staff members as specified in section 20-01-02-01(36)-(39).</u></p> <p>20-02-01-05 subsection 9(c) <u>highlighted: area of concern</u> c. <u>During the administration of deep sedation or general anesthesia the anesthesia permit provider and at least two other individuals: One individual to assist the (host) dentist as necessary. One individual solely responsible to assist with observation and monitoring of the patient. This individual shall be a class I or II dental anesthesia assistant permit holder as provided in 20-03-01-05 or the anesthesia permit provider if utilized by a host dentist.</u></p>	J. Glosenger, DDS, OMFS	<p>Dr. Glosenger believes the sections conflict with each other because 9c lays out new information on the team members and limits the team to an RDA or RDH as it requires the staff to have the Class I or II permit. Dr. Glosenger does not support this because:</p> <p>Protection of the public. A QDA who has taken the DAANCE course and passed their exam also has ACLS, BLS, and PALS (Advanced Cardiac Life Support, Basic Life Support and Pediatric Advanced Life Support). Their training prepares them for an emergency situation as might occur in a dental setting, but they are not eligible under current rule to take the DAANCE and obtain the CL I or II permit. The section also prevents an RN, LPN, or paramedic from assisting in a surgical setting yet are highly trained to do so. Currently these health providers are used to monitor vital signs during surgical procedures.</p> <p>Dr. Glosenger suggests the NDBDE consider that a QDA may become certified by DAANCE. The OMFS office trained dental assistant does not need RDA certification and have nothing to gain by learning the techniques for restorative four-handed dentistry as they work in the oral surgery setting. DANB exam has a very small portion related to surgical setting and DAANCE does a far better job of that.</p> <p>Re 20-03-01-01.(5r) duties under general supervision The board should consider the difference between fixed crown and bridge and simply scanning an abutment on an implant, the scanner is taking 500 pictures and using an algorithm to produce a 3D image. Scans are far more accurate than other types of impressions used for crown and bridge.</p> <p>Monitor a patient who has been induced to moderate sedation, <u>deep sedation</u> or general anesthesia until the dentist authorized by permit to administer sedation or anesthesia determines the patient may be discharged for recovery.</p> <p>20-03-01-02(12) <u>12. Unless authorized by permit in accordance with section 20-03-01-05.1, Monitor a patient who has been induced to a level of moderate sedation, or deep sedation or general anesthesia until the dentist authorized by permit to</u></p>



<p>20-03-01-01.(5r) duties under general supervision  <u>r. Produce on a patient of record, a final scan by digital capture for review by the authorizing dentist for a prescriptive fixed or removable appliance.</u></p> <p>20-03-01-02(12) <u>12. Unless authorized by permit in accordance with section 20-03-01-05.1, Monitor a patient who has been induced to a level of moderate sedation, or deep sedation or general anesthesia until the dentist authorized by permit to administer sedation or anesthesia determines that the patient may be discharged for recovery.</u></p>		<p><u>administer sedation or anesthesia determines that the patient may be discharged for recovery.</u></p> <p>Every national standard that exists states the anesthesia provider must be with patient for whom they have induced anesthesia for the duration of the anesthetized state, until they are appropriately responsive. Dr. Glosenger asserts the language for the hygienists is better. He does not think it is the Board's intention to allow an RDA or RDH to monitor a patient who has been induced to general anesthesia without the doctor in the room.</p> <p>Dr. Glosenger also commented on the workforce, shortages of RDH, RDA or people that just want to work. There are many that require our services, and we need to treat them safely and if we are too prescriptive and have require credentials for tasks they are not performing, we will further limit the dental workforce.</p> <p>Page 30 -14. The Board uses "American Heart Association" when other providers do equally as well. It may be impossible for this organization to provide instructors or classes at times or places they are needed. Elsewhere we allow other providers and do not want to favor one when others may be more accessible. Rather set quality standards such as hands-on courses.</p>
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#### BOARD RESPONSE TO COMMENT:

Regarding the comment related to use of the language "American Heart Association," the Board identifies other entities as well as stating that other equivalent courses would be acceptable and has consistently accepted CE from the American Red Cross, i.e., the Board's definition of Cardiopulmonary resuscitation course where the definition accepts an equivalent course. Similar language can be found in section 20-02-01-05. Dr. Tanabe commented that the committee that makes recommendations for life support is not associated with American Heart Association (AHA). The AHA takes the information and extrapolates it into a course. No changes were recommended by the Board for this comment.

Regarding 20-02-01-05 subsection 9(c) **highlighted: area of concern** the Board determined that the section could be removed as there simply are not that many dental anesthesia assistants available while other non-dental, but adequately educated and trained individual are available.

c. During the administration of deep sedation or general anesthesia the anesthesia permit provider and at least two other individuals: One individual to assist the (host) dentist as necessary. One individual solely responsible to assist with observation and monitoring of the patient. This individual shall be a class I or II dental anesthesia assistant permit holder as provided in 20-03-01-05 or the anesthesia permit provider if utilized by a host dentist.

The section also implies that only an RDH or RDA can become the anesthesia assistant. Some anesthesia assistants employed by offices where oral surgery is provided are EMT (emergency medical technician) trained. Other health care providers are excluded as well.

c. During the administration of deep sedation or general anesthesia the anesthesia permit provider and at least two other individuals: One individual to assist the (host) dentist as necessary. One qualified dental staff member solely responsible to assist with observation and monitoring of the patient. This individual shall be a class I or II dental anesthesia assistant permit holder as provided in 20-03-01-05 or the anesthesia permit provider if utilized by a host dentist. In motion #8, the Board addressed Dr. Glosenger's concerns related to the limited staff available to provide anesthesia and sedation assistance to the sedation provider. OMFS often use nurses if they are available which is not always the case. Dr. Tanabe concurred that the issue is something many OMFS encounter and is a patient safety concern. This issue is another avenue for the board to ensure safety in the provision of anesthesia as the Board ensures adequate certifiable training and education is practical for auxiliary to obtain. In new section 20-02-01-05 (9)(c) the rules require a dental assistant must be in the room during the administration of deep sedation or general



anesthesia. One individual to assist the dentist and one qualified dental staff member will be required to assist with monitoring the patient in the administration of deep sedation or general anesthesia.

The Board agreed with Dr. Glosenger request regarding duties for a final scan by digital capture for review by the authorizing dentist for a prescriptive fixed or removable appliance to apply also to Qualified Dental Assistants and the section was amended.

NDAC SECTION ADDRESSED AND/OR CONCERN	COMMENTATOR	SUMMARY OF COMMENT
20-03-01-05.2  Endorsement and support. Also remain concerned regarding on the job hours required to be registered as a Qualified Dental Assistant.	Sasha Dusek, RDA, North Dakota Dental Assistants' Association (NDDAA)	The NDDAA supports the Board's Administrative Rules efforts. However, the organization remains in disagreement with the reduction of hours required to become a Qualified Dental Assistant and is supportive of all other amendments.

**BOARD RESPONSE TO ORAL COMMENT:**

The NDDAA remains concerned regarding 300 rather than 650 hours of on-the-job training. The Board moved to change the on-the-job hourly requirement to 300 hours in recognition of any applicant successfully completing the Dental Assisting National Board's (DANB) National Entry Level Dental Assistant (NELDA) examination. The Board consensus was that not only is the reduction in hours appropriate, safe and fair, the three components of the NELDA exam ensure that entry level dental assistants have the basic level of knowledge necessary *for the level of duties they may perform*. The exam includes an additional component not previously required that addresses anatomy, morphology and physiology. The NDBDE accepts the Dental Assisting National Board's (DANB) National Entry Level Dental Assistant (NELDA) pathway as a valid and reasonable pathway for entry level dental assisting that assesses the knowledge required for performing duties that an entry level dental assistant is authorized to provide when coupled with 300 hours of clinical experience. The Board recognizes that entry level dental assistants must spend numerous hours of study preparing for the exam. In exchange for successful completion of the NELDA examination, it wishes to recognize that 300 hours rather than 650 hours of clinical experience is a reasonable time period to grasp basic dental assisting duties as provided by NDAC 20-03-01-01. The Board considered input from both dental assistants and DANB to arrive at the 300-hour requirement.

NDAC SECTION ADDRESSED AND/OR CONCERN	COMMENTATOR	SUMMARY OF COMMENT
20-03-01-01 (1)(k)	Robert Zena, DMD, Past President of the American Association of Dental Boards	Dr. Zena supports new technology.

**BOARD RESPONSE TO ORAL COMMENT:**

The Board reviewed the comment, and the Board has addressed the comment regarding telehealth as shown above in the responses to comments from Doctor's Ackerman, Sulitzer and Mr. Andrist's and Mr. Lawrence's comments. The Board has amended those rules based on comments, opinions and perspectives reviewed.



## BOARD ACTIONS

### Motion #1: NDAC §§ 20-01-02-1(38); 20-03-01-05(2)

Dr. Dohm moved to approve the following changes, motion seconded by Ms. Marsh. Hearing no further discussion, RCV: Mr. Mehlhoff, yes; Ms. Marsh, yes; Ms. Carlson, yes; Dr. Dohm, yes; Dr. Tanabe, yes; Dr. Kangas, yes; Dr. Fallgatter, yes. Motion carried, 7-0.

38. "Qualified dental assistant" means a dental assistant who has been employed and trained as a dental assistant and has received at least ~~six~~ three hundred fifty hours of on the job training, and successfully completed a board approved infection control seminar and passed the national entry level dental assistant certification administered by x-ray, infection control, and dental anatomy portions of the dental assisting national board examination, or other board approved course, and has applied to the board and paid the certificate fee and met any other requirements of section 20-03-01-05.

Ms. Marsh commented on deleting the 300 hours from pathway #3 because of the requirements of the ND Dept of Career Technical Educations layer of requirements for the program. The Board also deleted language related to the ND institution to safeguard those students who may take the education out of state.

2. The board may grant registration as a qualified dental assistant to an applicant meeting all the following requirements:
  - a. The applicant meets any of the following requirements:
    - (1) The applicant passed the ~~infection control and radiation parts of~~ national entry level dental assistant certification administered by the dental assisting national board examination and completed 300 hours of on-the-job clinical training within one year of application.
    - (2) The applicant passed the ~~infection control and radiation parts of~~ national entry level dental assistant certification administered by the dental assisting national board examination, 300 hours of on-the-job clinical training, and completed within two years before application, sixteen hours of continuing education in accordance with section 20-03-01-06.
    - (3) The applicant successfully completed the national entry level dental assistant certification administered by the dental assisting national board and successfully completed the North Dakota State Department of Career Technical Education dental assisting education program association or board approved equivalent course offered by a North Dakota institution of higher education and submits evidence of 300 hours of on-the-job clinical training within one year of application.
    - (4) The applicant completes a board approved equivalent course within one year of application.

### Motion #2: NDAC § 20-03-01-01(2)

Ms. Marsh moved that 20-03-01-01(2) be amended by striking "on a patient of record" as follows:

2. A qualified dental assistant may perform the duties set forth in subsection 1 and take dental radiographs on a patient of record under the direct supervision of a dentist, produce on a patient of record a final scan by digital capture for review by the authorizing dentist under general supervision for a prescriptive, fixed or removable appliance.

Dr. Kangas seconded the motion. Hearing no further discussion, RCV: Mr. Mehlhoff, yes; Ms. Marsh, yes; Ms. Carlson, yes; Dr. Dohm, yes; Dr. Tanabe, yes; Dr. Kangas, yes; Dr. Fallgatter, yes. Motion carried, 7-0.

### Motion #3: NDAC § 20-03-01-01(2)

Following the discussion and because the Board believes clinical knowledge is required for the procedure, the Board amended subsection 2 which more appropriately addresses the issue. Ms. Marsh moved that 20-03-01-01(2) be amended as follows:

2. A qualified dental assistant may perform the following duties: set forth in subsection 1 and take dental radiographs under the direct supervision of a dentist.
  - a. Duties set forth in subsection 1 of this section under the direct supervision of a dentist.



b. Take dental radiographs under the direct supervision of a dentist.

c. Produce on a patient of record a final scan by digital capture for review by the authorizing dentist under general supervision for a prescriptive, fixed or removable appliance.

Discussion; Ms. Marsh provided a point of clarification; the amendment would apply to orthodontic appliances as well as other fixed or removable appliances. Ms. Carlson seconded the motion. RCV: Mr. Mehlhoff, yes; Ms. Marsh, yes; Ms. Carlson, yes; Dr. Dohm, yes; Dr. Tanabe, yes; Dr. Kangas, yes; Dr. Fallgatter, yes. Motion carried, 7-0.

#### **Motion #4: NDAC § 20-03-01-01(1)(k)**

To further address the "patient of record" concern, the Board amended rule 1.k. by striking "on a patient of record" because the concept of "patient of record" applies to the entire section 1 as dental assistants not regulated must work under the direct supervision of a dentist. Including "on a patient of record" is there for already understood and need not be specifically included in this section.

Dr. Dohm moved and Dr. Tanabe seconded a motion to strike "on a patient of record"

1.(k.) Take dental photographs including the use of intraoral cameras on a patient of record.

Hearing no further discussion, RCV: Ms. Carlson seconded the motion. Hearing no further discussion, RCV: Mr. Mehlhoff, yes; Ms. Marsh, yes; Ms. Carlson, yes; Dr. Dohm, yes; Dr. Tanabe, yes; Dr. Kangas, yes; Dr. Fallgatter, yes.

#### **Motion #5: NDAC § 20-02-01-09(2)(j)**

Related to Mr. Andrist's comment; Dr. Dohm moved that the Board leave the language of section 20-02-01-09 (2)(j) as is because the language is in harmony with the ND Century Code 43-28-11.3(2). Motion seconded by Dr. Tanabe.

Hearing no further discussion, RCV: Mr. Mehlhoff, yes; Ms. Marsh, yes; Ms. Carlson, yes; Dr. Dohm, yes; Dr. Tanabe, yes; Dr. Kangas, yes; Dr. Fallgatter, yes. Motion carried, 7-0.

#### **Motion #6: NDAC § 20-03-01-01(1)(k)**

Dr. Dohm moved, motion seconded by Mr. Mehlhoff to acknowledge Dr. Zena's comments which the Board has previously acted upon by amending rules. Hearing no further discussion, RCV: Dr. Kangas, yes; Ms. Marsh, yes; Ms. Carlson, yes; Dr. Dohm, yes; Dr. Tanabe, yes; Mr. Mehlhoff, yes; Dr. Fallgatter, yes. Motion carried, 7-0.

#### **Motion #7: NDAC §§ 20-02-01-09(2)(j) and 20-03-01-01(1)(k)**

Moved by Dr. Dohm to acknowledge the comments of the AAO and the Board is appreciative and thank the AAO for their support. The Board feels we have addressed their concerns in the best manner possible considering comments from all parties. Dr. Tanabe seconded the motion. Hearing no further discussion, RCV: Dr. Kangas, yes; Dr. Tanabe, yes; Mr. Mehlhoff, yes; Dr. Dohm, yes; Ms. Carlson, yes; Dr. Fallgatter, yes. Ms. Marsh, yes. Motion carried, 7-0.

#### **Motion #8: NDAC § 20-02-01-05.1(9)(c)**

Dr. Tanabe moved to delete language which conflicts with other areas of statute by providing new information on the team members and which limits the staff for the position to a registered dental hygienist or registered dental assistant. Dr. Dohm seconded the motion. Discussion; Alternatively the Board considered a new definition for a dental sedation assistant (DSA) as defined in the definition and the criteria for qualifications of the DSA (dental sedation assistant).

highlighted: area of concern the Board determined that the section could be removed as there simply are not that many dental anesthesia assistants available. 20-02-01-05 subsection 9

c. During the administration of deep sedation or general anesthesia the anesthesia permit provider and at least two other individuals: One individual to assist the (host) dentist as necessary. One individual qualified dental staff member solely responsible to assist with observation and monitoring of the patient. This individual shall be a class I or II dental anesthesia assistant permit holder as provided in 20-03-01-05 or the anesthesia permit provider if utilized by a host dentist.

#### **Motion #9: NDAC §§ 20-03-01-01.1; 20-03-01-01.2 and NDAC § 20-01-02-01(18)**

Dr. Tanabe moved to create a new definition for a *dental sedation assistant* as defined in NDAC § 20-01-02-01. Motion seconded by Dr. Dohm. Discussion: The new qualified dental staff member would be specific to sedation and anesthesia. Language for dental sedation assistant can be found in the dental assisting section



20-03-01.1(2) and (3). The Board may expand on the definition in the future. Dr. Tanabe views the new form of assistant as a much-needed layer of patient safety and allows the dental practitioner to have office staff specific to anesthesia and sedation and providers. Eventually the Board may require all offices to have the minimum level of sedation and anesthesia training for staff in the sedation setting. Hearing no further discussion, RCV: Dr. Kangas, yes; Dr. Tanabe, yes; Mr. Mehlhoff, yes; Dr. Dohm, yes; Ms. Carlson, yes, Dr. Fallgatter yes. Ms. Marsh, yes. Motion carried, 7-0. The issue also addresses concerns of Dr. Glosenger.

18. "Dental anesthesia assistant" means an individual who possesses the expertise to provide supportive anesthesia care in a safe and effective manner. The anesthesia assistant is educated in the perioperative and emergent care management of patients undergoing dental office sedation and anesthesia.

**Motion #10: NDAC § 20-02-01-05(14)(c )(5); NDAC § 20-02-01-05(13)**

Dr. Tanabe moved that the age for pediatric patients be changed from 10 years to 8 years of age. Discussion; The measure aligns the Board with the recommendation of Pediatric Life support guidelines. Motion seconded by Dr. Dohm. Hearing no further discussion, RCV: Dr. Kangas, yes; Dr. Tanabe, yes; Mr. Mehlhoff, yes; Dr. Dohm, yes; Ms. Carlson, yes, Dr. Fallgatter yes. Ms. Marsh, yes. Motion carried, 7-0.

**Motion #10: NDAC § 20-02-01-05(3)(f)**

Mr. Mehlhoff moved to make a correction to NDAC § 20-02-01-05(3)(f) as follows:

f. Administering intranasal versed and or fentanyl shall be considered moderate deep sedation. Rules for deep sedation and general anesthesia site evaluations shall apply for administration of intranasal versed and or fentanyl. Dr. Dohm seconded the motion. Hearing no further discussion, RCV: Dr. Kangas, yes; Dr. Tanabe, yes; Mr. Mehlhoff, yes; Dr. Dohm, yes; Ms. Carlson, yes, Dr. Fallgatter yes. Ms. Marsh, yes. Motion carried, 7-0.

Final comments: Ms. Carlson commented on the RPM of handpieces. The Board has studied the "handpiece" issue and has remained satisfied with assistants using slow speed handpieces although it has created issues with dental assistants who provide expanded functions restorative procedures. Ms Carlson commented that some offices are going to electric highspeed handpieces which can be dialed down and the hand piece may have a ratio. The maximum slow speed on an electric handpiece is 40,000 RPM. Dr. Kangas also addressed the torque issue. Dr. Dohm is interested in the language of other state laws regarding the issue before making a decision. The Board will study the issue further once information is available. Sasha Dusek, RDA commented on the 80-hour course at the U of MN. The course teaches students on the high-speed handpieces. No motion.

Dr. Dohm moved to adopt rule changes as discussed. Motion seconded by Dr. Fallgatter. Discussion; The ED will provide a copy of adopted rules and minutes to Board members once the documents are complete. Hearing no further discussion, RCV: Dr. Kangas, yes; Dr. Tanabe, yes; Mr. Mehlhoff, yes; Dr. Dohm, yes; Ms. Carlson, yes, Dr. Fallgatter, yes. Ms. Marsh, yes. Motion carried, 7-0.

Ms. Carlson moved to adjourn. Motion seconded by Dr. Fallgatter. All in favor. The meeting was adjourned at 10:33 PM.

The next meeting of the Board will be held virtually April 22, 2022.

Submitted by Rita Sommers, RDH, MBA

Marcus Tanabe, DDS, OMFS, NDBDE Secretary-Treasurer

EXHIBIT "B"

Administrative Rules Committee  
Wednesday, June 1, 2022, 10:00 am  
Roughrider Room, State Capitol  
State Board of Dental Examiners

Re: Testimony in support of the Administrative Rules changes put forth by the State Board of Dental Examiners

Madam Chair Poolman and Members of the Administrative Rules Committee,

Good morning, my name is Dr. Marcus Tanabe. I am an Oral Surgeon who lives and practices in Grand Forks and currently serves as Chair of Anesthesia for the North Dakota Board of Dental Examiners. I wish to write in support of the dental examiners' administrative rule changes.

A significant portion of the rules change deals with the administration of anesthesia in the dental office. As you are aware, this is a valuable service for the underserved dental population who are a group that often present with a dental phobia. However, the use of dental anesthesia must be safeguarded with appropriate regulation. These new dental rules bring the State of North Dakota dental practice in line with other state and anesthesia practice guidelines that have been put forth by dental and anesthesiology associations.

One of the proposed rule changes would put us at the forefront of the dental anesthesia community and improve the outcomes of adverse anesthesia events. We have proposed that all North Dakota dental anesthesia providers take an emergency simulation course with their staff every five years. These full-body simulation mannequins would be able to provide the most realistic practice of anesthesia emergencies. This would be the same patient simulator and cases scenarios that anesthesiologists and nurse anesthetists already perform on a regular basis at our local hospitals. Being a regular anesthesia provider myself most cases go smoothly, but incidents do arise and being able to recognize and treat in timely manner is imperative for positive outcomes. Anesthesia is high stakes but valuable part of dentistry. Anesthesia must be actively regulated to ensure that all dental patients are being treated with the highest level of care.

If you have any more questions or would like to speak further about the proposal, please do not hesitate to contact me.

Sincerely,  
Dr. Marcus B Tanabe DDS  
North Dakota Board of Examiners  
Chair of Anesthesia

# Exhibit 14



## The Grin Life



CONVENIENCE, GETTING STARTED, WHY SMILEDIRECTCLUB, YOUR SMILE JOURNEY™

## SmileDirectClub's Partner Network

If you think SmileDirectClub means you're on your own when it comes to creating your new smile, think again.

### An option that's right for you

While many club members choose to use our [Impression Kit](#) to get their custom-made aligner, that's just one of **three** options to get you started.

## The Grin Life

And now there's a third option: Going to one of the 1,500+ dentists and orthodontists in SmileDirectClub's Partner Network. These doctors partner with SmileDirectClub to help provide clear aligner therapy to customers. These doctors will get you started on your Smile Journey™ right in their office. The doctors can be found throughout the country and can give you personalized advice and guidance to give you more confidence before starting your treatment.



### Why choose the Partner Network?

Visiting a dentist in our Partner Network is a great way to establish care with a local dentist and an easy way to ensure your teeth are healthy throughout your journey. With the Partner Network, there are even more locations for you to choose from, so it's more convenient than ever to get started with an in-person visit.

By using a dentist or orthodontist in our Partner Network, you get the same benefits, and a personal touch. They'll take a 3D image or impression of your teeth in their office, talk through your options, and explain how the treatment works.

## The Grin Life

And you can visit one of these dentists with confidence that you'll get [great dental care](#) throughout your treatment with SmileDirectClub, and long after, too. Your [oral health](#) is always important and even more so while you're undergoing orthodontic treatment.

You'll be under SmileDirectClub's care for your aligner treatment. Your individual treatment plan will be prescribed, directed, and managed by a state-licensed doctor. Your check ins will be virtual through SmileDirectClub's [teledentistry](#) platform. You won't have to go in to any office for follow up office visits regarding your aligners, but you can set up regular cleaning appointments with your Partner Network doctor.

However you would like to start off your Smile Journey, SmileDirectClub has an option for you. A full list of participating Partner Network doctors will be available soon.

If you are a provider and would like to learn more about joining our Partner Network, please check out our website [here](#).

### PREVIOUS ARTICLE

[Learn the lingo you'll hear during your treatment](#)

### NEXT ARTICLE

[Science says your oral health is key to your well-being](#)

## You may also like

## The Grin Life

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What is a 3D image?

## The Grin Life

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## Join the Club

Get started now with our free and easy Smile Assessment.

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### FAQ

# The Grin Life

## LOCATIONS

### Am I A Candidate?

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# Exhibit 15

# Expanding into clear aligners for practice growth.



Loray Spencer, DDS, and Harvey Spencer, Jr., DDS  
A Healthy Smile Dentistry in Rock Hill, South Carolina

**Dr. Loray Spencer and Dr. Harvey Spencer of A Healthy Smile Dentistry in Rock Hill, South Carolina,** pride themselves on being a one-stop solution for all their patients' dentistry needs, including orthodontia, while providing compassionate care. However, teeth straightening remains out of reach for so many. The husband-and-wife duo recently decided to grow their practice by introducing a more accessible option that helps more patients experience the life-changing health benefits that come with a new smile.

"With so many teeth straightening options available, quality remains a key focus for our practice," said Dr. Harvey Spencer. "It's important that our patients know that they are receiving the best care possible and the finest dentistry when they sit in our chair."

The doctors wanted a solution that would give their patients a more affordable and convenient option, easily integrate within their office without added overhead, and help grow their practice by increasing new patient volume.

After thorough research, A Healthy Smile Dentistry joined the **SmileDirectClub Partner Network** to offer a clear aligner solution that matched their needs. SmileDirectClub's hybrid aligner model allows dentists to make orthodontic treatment accessible to a wider range of patients, including those who may not have been able to afford other orthodontic treatments, have had relapses from prior orthodontic treatment, or simply do not have the time for frequent visits to the dental office. The unique hybrid model allows patients seeking clear aligner treatment to start their journey at a dentist's office and complete treatment conveniently through SmileDirectClub's pioneering telehealth platform that has helped over 1.5 million customers and counting.



## Benefits of the partnership.

- Increasing revenue by expanding your clear aligner offering with a more affordable option.
- Growing your practice by increasing the volume of new patients your practice intakes.
- Receiving valuable marketing support that can help increase awareness for your practice—all at no cost to you.
- Reaching a new segment of patients who have not been able to access orthodontic care.

"With so many teeth straightening options available, quality remains a key focus for our practice."

—Dr. Harvey Spencer

The patient information collected at the dental office is submitted to SmileDirectClub's telehealth platform, where SmileDirectClub affiliated state-licensed doctors assess clear aligner candidacy and prescribe and monitor treatment from beginning to end. Patients can review their treatment plan and receive their aligners all



**“SmileDirectClub empowers us with the tools to successfully integrate clear aligner treatment into our office and even provides marketing materials to enable our practice growth; it’s a true partnership packaged in a turnkey process.”**

at once, mailed directly to them. There’s even a mobile app that helps monitor and encourage compliance, and regular telehealth check-ins ensure treatment progresses safely and as planned.

The Partner Network gives the Spencers the opportunity to offer a best-in-class option to those who have mild to moderate misalignments without sacrificing profitable chair time or in-office production. Offering treatment options increases patient retention and empowers patients to make their own decisions about their care.

SmileDirectClub Partner Network offices also benefit from unprecedented marketing support aimed at helping grow each practice and boost brand awareness. The Spencers know that their patients have many options, and the marketing expertise from SmileDirectClub offers an advantage and attracts new patients to

their office—for clear aligners, as well as for overall orthodontics and restorative and hygiene procedures.

“One of the major selling points for us was the ease of the process,” added Dr. Loray Spencer. “SmileDirectClub empowers us with the tools to successfully integrate clear aligner treatment into our office and even provides marketing materials to enable our practice growth; it’s a true partnership packaged in a turnkey process.”

In this new era of dentistry, where clear aligner therapy and telehealth have merged, the opportunities are endless for practice growth and for transforming the lives of patients.

“We are excited to expand our practice and welcome more members of the community to our chair,” said Dr. Loray Spencer.

**See the same success at your practice. Join today.**

**[SmileDirectClub.com/Partner-Network](https://SmileDirectClub.com/Partner-Network)**

# Exhibit 16



March 11, 2019

**VIA FEDERAL EXPRESS**

David Steven Eshom, Dental Corporation  
Attn: Dr. David Eshom  
8899 University Center Ln, Ste 245  
San Diego, CA 92122

Mark W Orlando  
David Steven Eshom, Dental Corporation  
312 N Palm Canyon Dr.  
Palm Springs, CA 92262

RE: DEMAND TO IMMEDIATELY CEASE AND DESIST  
IMMEDIATE ATTENTION REQUIRED

Dr. Eshom:

I write as legal counsel for SmileDirectClub, LLC and its affiliated entities ("SDC"). The purpose of this letter is to formally demand that you and David Steven Eshom, Dental Corporation (collectively the "Company") immediately cease making false and inaccurate statements regarding SDC. It is clear that the Company is either misinformed or are intentionally making false and deceptive statements in a manner intended to scare away actual and potential SDC customers and unlawfully profit from and compete with SDC for those customers.

We recently became aware of a YouTube video posted on 3/6/19 featuring you that contains false and deceptive statements, which can be found at this link: <https://www.youtube.com/watch?v=ubOPe8D3LU> ("Video"). A screenshot is attached hereto as Exhibit A.

In the title below the Video, it states, "Smile Direct compared to Invisalign compared to DIY orthodontics" directly above your name and a subscribe link to the your YouTube channel. The description of the Video refers to SDC's services and products, albeit indirectly, in the following manner: "Do it yourself" orthodontics (DIY) is dangerous because of lack of supervision by trained lice [sic] doctors. Anything less in quality and supervision leads to a [sic] unsatisfied patient or an unhealthy bite or both..." In the Video, you make several claims that are clearly and unambiguously false about SDC's services and products, including that SDC's customers are not supervised by licensed dentists, that the customers do not get diagnosed and that no one is going to supervise healthy movement of teeth while a customer is utilizing aligner therapy, among other claims.





Contrary to allegations in your Video, each and every candidate wishing to use SDC's teledentistry platform<sup>1</sup> is evaluated by a dentist or orthodontist licensed in that candidate's state (the "Treating Doctor"). If the Treating Doctor determines, in his or her sole discretion, that such potential patient is a viable candidate for clear aligner therapy treatment, the Treating Doctor oversees and monitors all clinical aspects of their patient's care throughout the course of treatment, including ninety (90) day check-ins to monitor movement of each individual's teeth and results.

Further, your distinction as to the differences in aligner material is false. We note that Align is our exclusive third party manufacturer of SDC aligners.

You also challenge scans by companies such as SDC, presumably referencing iTero scans that are taken at SDC SmileShops, as being 'less accurate' and that they trays therefore 'fit worse'. Such statement are unfounded and false.

By making the foregoing false and deceptive claims, the Company is committing false advertising in violation of the Lanham Act, 15 U.S.C. § 1125(a). 15 U.S.C. § 1125(a)(1)(B) states in pertinent part:

Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce ... false or misleading description of fact, or false or misleading representation of fact, which ... in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

By making false and deceptive statements, the Company also violates California law regarding, at least, unfair competition, tortious interference and defamation. Violations of the Lanham Act and/or state laws subject you to exposure for SDC's monetary damages, your wrongful profits, injunctive relief, treble

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<sup>1</sup> Each potential patient seeking to use the SDC teledentistry platform is provided a written consent that duly informs them of the teledentistry platform and the risks involved with clear aligner therapy treatment.





damages, punitive damages, attorneys' fees and expenses, and/or the costs of bringing a lawsuit against the Company.

SDC takes your false and deceptive statements very seriously. SDC therefore demands that the Company immediately remove the above-referenced Video description of SDC, as well as any related posts on the Company's website(s). SDC further demands that you immediately remove all other postings, blogs, marketing material, and any other publicly available source that contain any and all false and misleading statements made by the Company that refer to SDC.

Please confirm in writing by March 15, 2019, at 5:00 p.m. Central that the Company has taken the above-referenced actions. We are available to discuss this matter at your convenience.

Nothing herein is intended nor should be construed to be a waiver of any right, claim, and/or defense.

Sincerely,

A handwritten signature in blue ink, appearing to read "Chase D. Fisher".

**Chase D. Fisher**  
Senior Litigation Counsel  
SmileDirectClub  
Chase.Fisher@smiledirectclub.com  
(615) 601-3287  
414 Union St, 8th Floor  
Nashville, TN 37219

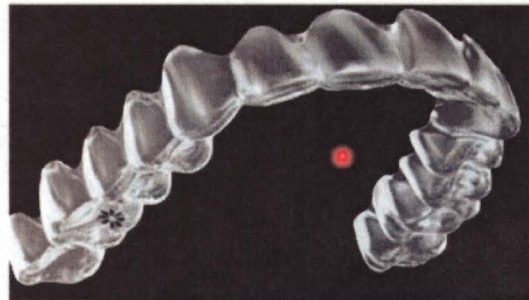
Enclosure



Exhibit A



## Cost Analysis



You get what you pay for!!!

[www.SanDiego-Invisalign.com](http://www.SanDiego-Invisalign.com)

858 455-9151



Smile Direct compared to Invisalign compared to DIY orthodontics

15 views

0 0 SHARE SAVE ...



David Eshom

Published on Mar 6, 2019

SUBSCRIBE 553

Paitents now have a huge choice in clear orthodontic aligner companies but that may be confusing to patients. In this video, you will be informed of the differences in the companies and methods. There is a big difference in the service, supervision and tray plastics the makes the outcome (ie.

# Exhibit 17

## SUS VOLUNTARY EVENT REPORT (FOI for Manufacturers)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5090518	SMILEDIRECTCLUB / ALIGN TECHNOLOGY, INC.	21-OCT-2019	22-OCT-2019 11:23:55.00

## Event Information

Event Date (B3):	11-OCT-2019	Event Report Type (H1):	Serious Injury	Adverse Event (B1):	Y
Report Date (B4):	17-OCT-2019	Event Outcome (B2):	Disability/Permanent Damage		
		Reporter Occupation (G3):	DENTIST		
Problem (B1):	N				

## Device Information - 1

Product Code (E2b):	ALIGNER, SEQUENTIAL (NXC)		
Brand (E1):	SMILE DIRECT CLUB		
Device Type (E2):	ALIGNER, SEQUENTIAL		
Model #(E4):		Other # (E4):	
Catalog #(E4):		Lot # (E4):	
		Implant Date (E6):	
		Explant Date (E7):	
Expiration Date (E4):		Single Use (E8):	I
Device Available for Evaluation (C):	Y	Date Device Returned to Mfr (C):	

## Mfr Contact Name and Address (E3)

E3 ? Mfr Name:	SMILEDIRECTCLUB / ALIGN TECHNOLOGY, INC.
Address (E3):	UNITED STATES

## SUS VOLUNTARY EVENT REPORT (FOI for Manufacturers)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Description****(B5):****Date FDA received:** 21-OCT-2019

Voluntary 22-OCT-2019 11:23:55.00:

THIS PT PRESENTED WITH TMJ PAIN AFTER STARTING ORTHODONTIC TREATMENT WITH SMILE DIRECT CLUB. THE PT BEGAN INAPPROPRIATE ORTHODONTIC TREATMENT WITHOUT THE CONSULTATION OF A DR. THE PT REPORTED TO THE EMPLOYEES AT SMILE DIRECT CLUB THAT SHE HAD NOT SEEN A DENTIST IN YEARS AND THAT SHE HAD A HISTORY OF TMJ PAIN. THEY DISREGARDED THIS INFO AND BEGAN TREATMENT ANYHOW. ALONG WITH THIS, THE TREATMENT THEY HAD PROPOSED AND BEGAN WAS ENTIRELY INAPPROPRIATE CARE FOR THIS PT DUE TO HER SKELETAL PROFILE, OCCLUSION AND HISTORY OF TMJ PAIN. THE ORTHODONTIC TREATMENT DIRECTLY CONTRIBUTED TO SEVERE MUSCLE AND JOINT PAIN. HAD SHE CONTINUED WITH TREATMENT SHE WOULD HAVE A WORSENING OF HER OCCLUSION AND TMJ PAIN. SHE WOULD ALSO HAVE LIP INCOMPETENCE DUE TO THE PROPOSED TOOTH MOVEMENTS AS SHE WAS STRUGGLING TO KEEP HER LIPS TOGETHER WHILE AT REST WITH THE TOOTH MOVEMENTS ALREADY ACHIEVED. THE PT SHOULD BE UNDER THE CARE OF A LICENSED ORTHODONTIST AND IS ALSO A CANDIDATE FOR ORTHOGNATHIC SURGERY TO APPROPRIATELY TREAT HER MALOCCLUSION. FDA SAFETY REPORT ID# (B)(4).

**Concomitant Medical****Products (F):****INITIAL REPORTER INFORMATION (G)****Name (G1):**

[REDACTED]

**Company (G1):****Email (G1):**

[REDACTED]

**Address (G1):**

[REDACTED]

**Phone (G1):**

[REDACTED]

**Fax (G1):**

[REDACTED]

UNITED STATES

**Health Professional (G2):**

Y

**Also Reported To (G4):**

Manufacturer:  
User Facility: N  
Distributor/Importer:  
N

**Occupation (G3):**

DENTIST

**NOT Releasable (G5):**

# Exhibit 18



## SUS VOLUNTARY EVENT REPORT (FOI for Manufacturers)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5090487	SMILEDIRECTCLUB / ALIGN TECHNOLOGY, INC.	18-OCT-2019	21-OCT-2019 11:32:00.00

## Event Information

Event Date (B3):	08-MAY-2019	Event Report Type (H1):	Serious Injury	Adverse Event (B1):	Y
Report Date (B4):	16-OCT-2019	Event Outcome (B2):	Disability/Permanent Damage,Other Serious (Important Medical Event)		
		Reporter Occupation (G3):	DENTIST		
Problem (B1):	Y				

## Device Information - 1

Product Code (E2b):	ALIGNER, SEQUENTIAL (NXC)		
Brand (E1):	SMILE DIRECT CLUB ORTHODONTIC ALIGNERS		
Device Type (E2):	ALIGNER SEQUENTIAL		
Model #(E4):		Other # (E4):	
Catalog #(E4):		Lot # (E4):	
		Implant Date (E6):	
		Explant Date (E7):	
Expiration Date (E4):		Single Use (E8):	I
Device Available for Evaluation (C):	Y	Date Device Returned to Mfr (C):	

## Mfr Contact Name and Address (E3)

E3 ? Mfr Name:	SMILEDIRECTCLUB / ALIGN TECHNOLOGY, INC.
Address (E3):	

## SUS VOLUNTARY EVENT REPORT (FOI for Manufacturers)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Description**

(B5):

**Date FDA received:** 18-OCT-2019

Voluntary 21-OCT-2019 11:32:00.00:

THIS PT IS CURRENTLY IN TREATMENT WITH ALIGNER FROM SMILE DIRECT CLUB AND IS CURRENTLY WEARING THE LAST SET OF ALIGNERS. HE HAS A HISTORY OF PREVIOUS ORTHODONTIC TREATMENT DUE TO EXTRACTIONS DONE WHILE HE WAS IN THE MILITARY; #6 IS BADLY ANKYLOSED (VER CLEAR ON THE PERCUSSION TEST AND ON A PANORAMIC X-RAY) AND THERE IS ZERO CLINICAL MOBILITY EITHER. THERE ARE STILL SPACES AT #4/6, 12/14 AND 19/21. THROUGH THE MEDICAL HISTORY, IT WAS DETERMINED THAT A BLOCK SEGMENT WAS ATTEMPTED FOR #6 IN THE PAST WITH NO LUCK AND THERE WAS EXTREME DIFFICULTY IN CLOSING THE SPACES WITH THE ANKYLOSIS AND ELAPSED TIME FROM THE EXTRACTIONS. THERE IS A NOTED UPWARD CANT FOR THE UPPER ANTERIOR TEETH AND THERE WAS MOVEMENT ATTEMPTED ON THE CANINE WITH THE ALIGNERS (BUT IS CLEARLY NOT FITTING IN THAT AREA). THERE ARE NUMEROUS AREAS OF MODERATE GINGIVAL RECESSON (AND THE TRAYS WERE DIGGING INTO A FEW AREAS WHICH IS NOT HELPING. THERE IS NOTED BRUXISM HABIT AND THE TRAYS ARE VERY HEAVILY WORN. RIGHT NOW THE ALIGNERS ARE DOING MORE HARM THAN GOOD. THIS IS TREATMENT BELOW THE STANDARD OF CARE. I HAVE SUPPORTING PHOTOGRAPHS OF THE IATROGENIC PROBLEMS CAUSE BY ALIGNER TREATMENT IN THIS PT. NO DIAGNOSTIC RECORDS SUCH AS A PANORAMIC X-RAY OR DENTAL HISTORY WAS OBTAINED PRIOR TO ALIGNER THERAPY. PLEASE FEEL FREE TO CONTACT ME IF YOU WOULD LIKE FURTHER DOCUMENTATION. I HAVE PHOTOS, A PANORAMIC X-RAY AS WELL AS A DETAILED DENTAL HISTORY TO DOCUMENT THE SUBSTANDARD CARE. FDA SAFETY REPORT ID# (B)(4).

**Concomitant Medical Products (F):** SMILE DIRECT CLUB STRAIGHTENING: (B)(6) 2018-(B)(6) 2019

**INITIAL REPORTER INFORMATION (G)****Name (G1):****Company (G1):****Email (G1):****Address (G1):****Phone (G1):****Fax (G1):****Health Professional (G2):**

Y

**Also Reported To (G4):**

Manufacturer:  
User Facility: N  
Distributor/Importer:  
N

**Occupation (G3):**

DENTIST

**NOT Releasable (G5):**

# Exhibit 19

## SUS VOLUNTARY EVENT REPORT (FOI for Manufacturers)

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Report Number	Manufacturer Name	Date FDA Received	Date FDA Added
MW5087549	SMILES DIRECT CLUB / ALIGN TECHNOLOGY INC.	21-JUN-2019	24-JUN-2019 11:15:08.00

## Event Information

Event Date (B3):	27-FEB-2019	Event Report Type (H1):	Serious Injury	Adverse Event (B1):	N
Report Date (B4):	19-JUN-2019	Event Outcome (B2):	Disability/Permanent Damage		
		Reporter Occupation (G3):	PATIENT		
Problem (B1):	Y				

## Device Information - 1

Product Code (E2b):	ALIGNER, SEQUENTIAL (NXC)		
Brand (E1):	SMILES DIRECT CLUB ALIGNERS		
Device Type (E2):	ALIGNERS, SEQUENTIAL		
Model #(E4):		Other # (E4):	
Catalog #(E4):		Lot # (E4):	
		Implant Date (E6):	
		Explant Date (E7):	
Expiration Date (E4):		Single Use (E8):	I
Device Available for Evaluation (C):	Y	Date Device Returned to Mfr (C):	

## Mfr Contact Name and Address (E3)

E3 ? Mfr Name:	SMILES DIRECT CLUB / ALIGN TECHNOLOGY INC.
Address (E3):	

## SUS VOLUNTARY EVENT REPORT (FOI for Manufacturers)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

## Device Information - 2

Product Code (E2b): ()

Brand (E1):

Device Type (E2):

Model # (E4):

Catalog # (E4):

Lot # (E4):

Other # (E4):

Implant Date (E6):

Explant Date (E7):

Expiration Date (E4):

Single Use (E8):

Device Available for  
Evaluation (C):Date Device Returned to Mfr  
(C):

## Mfr Contact Name and Address (E3)

E3 ? Mfr Name:

Address (E3):

## Event Description

(B5):

Date FDA received: 21-JUN-2019

Voluntary 24-JUN-2019 11:15:08.00:

AS A RESULT OF THE ALIGNERS OF SMILES DIRECT CLUB, I'VE SUSTAINED TEETH BREAKAGE AND LOSS OF A COUPLE OF TEETH. IN THE EMAIL BELOW (B)(6) INDICATES THAT THEY KNEW I HAD DAMAGE BEFORE THEY APPROVED THE ALIGNERS. COMMUNICATIONS VIA EMAIL WITH SDC: ON SATURDAY (B)(6) 2019 AT 10:45AM, CLINICALCARE@SMILEDIRECTCLUB.COM <CLINICALCARE@SMILEDIRECTCLUB.COM> WROTE: HI (B)(6), THIS IS (B)(6) WITH THE DENTAL TEAM FROM SMILES DIRECT CLUB. THANK YOU FOR REACHING OUT TO US. I AM SO SORRY YOU ARE HAVING ISSUES WITH NEEDED DENTAL WORK. OUR REMOTE CLEAR ALIGNERS DO NOT USUALLY CAUSE TEETH TO BREAK. I HAVE REVIEWED YOUR INITIAL SCANS WITH THE NEWEST SCANS WE HAVE ON FILE AND YOUR PHOTOS. I CAN SEE IN THE INITIAL PHOTOS. TOOTH #15 WAS BROKEN WHEN YOU STARTED REMOTE CLEAR ALIGNERS. TOOTH #16 DID HAVE A DARK AREA PRESENT ON THE MESIAL (FRONT SIDE) OF THAT TOOTH, THIS COULD HAVE BEEN POSSIBLE DECAY OR RECURRENT DECAY AROUND AN EXISTING FILLING THAT CAUSED THE TOOTH TO BREAK. TOOTH #13 APPEARS TO HAVE A DARK FRACTURE LINE ON THE OCCLUSAL SURFACE OF THE TOOTH THAT OVER TIME FRACTURED. TOOTH #31 WAS BROKEN WHEN YOU STARTED REMOTE CLEAR ALIGNERS. WHEN YOU STARTED REMOTE CLEAR ALIGNERS YOU SIGNED A RELEASE STATING YOU HAD HAD A DENTAL EXAM AND/OR XRAY'S COMPLETED WITH A LOCAL DENTIST. BEFORE YOU STARTED REMOTE CLEAR ALIGNERS THESE AREAS OF CONCERN SHOULD HAVE BEEN ADDRESSED WITH YOUR LOCAL DENTAL PROVIDER. IT IS RECOMMENDED YOU F/U WITH YOUR LOCAL DENTIST OR A RECOMMENDATION ON NEEDED TREATMENT AS WE DO NOT TREATMENT PLAN NEEDED EXTRACTIONS, CROWNS, OR FILLINGS AND ARE UNABLE TO PERFORM THE WORK NEEDED. IF YOU HAVE ANY QUESTIONS, PLEASE FEEL FREE TO CONTACT US AT (B)(6) , AS WE ARE HERE TO MAKE YOU SMILE. KINDEST REGARDS, (B)(6). DENTAL TEAM-RDH ON WEDNESDAY, (B)(6) 2019, 11:25:40 AM CST, <(B)(6)> WROTE: HI (B)(6), THIS IS (B)(6), ONE OF THE CUSTOMER CARE SPECIALISTS HERE AT SMILEDIRECTCLUB. WE HOPE THIS EMAIL FINDS YOU WELL. WE REALLY APOLOGIZE THAT YOU ARE NOT SATISFIED WITH THE OUTCOME AT THIS POINT. HOWEVER, WE WILL BE MORE THAN HAPPY TO ASSIST YOU. IN ORDER TO PROCESS YOUR REEVALUATION REQUEST, WE WILL NEED: A SERIES OF 3 PHOTOS WITHOUT YOUR ALIGNERS. A

## SUS VOLUNTARY EVENT REPORT (FOI for Manufacturers)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

DETAILED DESCRIPTION OF YOUR CONCERNS TO CORRECT BY REFERENCING TOOTH NUMBERS. WHAT ALIGNER NUMBER YOU ARE CURRENTLY WEARING AND THE DATE YOU BEGAN WEARING THIS ALIGNER. PLEASE, SUBMIT THE PHOTOS TO PHOTOS@SMILEDIRECTCLUB.COM AND ONCE WE HAVE RECEIVED THEM, WE WILL SUBMIT THE INFO TO YOUR STATE-LICENSED DR OR DR OVERSEEING YOUR CASE FOR FURTHER REVIEW AND WITHIN 3-5 BUSINESS DAYS, WE WILL GET BACK TO YOU WITH ADD'L INSTRUCTIONS. IF YOU HAVE ANY QUESTIONS, PLEASE FEEL FREE TO CONTACT US AT (B)(6). THANKS FOR BEING PART OF SMILEDIRECTCLUB AND WE HOPE YOU HAVE A GREAT DAY. KINDEST REGARDS, (B)(6) CUSTOMER CARE SPECIALIST (B)(6) SMILEDIRECTCLUB WWW.SMILEDIRECTCLUB.COM . FROM: (B)(6), SENT: TUE (B)(6) 2019 16:46:19 GMT-0600 (CENTRAL STANDARD TIME) TO: (B)(6) SUBJECT RE: (B)(6) - REEVALUATION HELLO (B)(6) , HERE'S MY PHOTOS WITH EXTRA SHOTS WITH THE EXTENT OF THE DAMAGE TO MY TEETH FROM THE ALIGNERS. LET ME KNOW IF THERE'S ANYTHING YOU REQUIRE. IF YOU STILL HAVE THE FACILITY THERE IN (B)(6) WHERE I TOOK THE INITIAL PHOTOS, I CAN GO THERE FOR CLEARER AND MORE THOROUGH PICTURES OF THE DAMAGE UPPER AND LOWER TEETH. FROM THE DENTAL CHART MY CONCERNS ARE FOR: THE BOTTOM TOOTH #31 MOLAR WHICH IS ALMOST NON-EXISTENT EXCEPT FOR THE BOTTOM PART OF THE TOOTH; THE UPPER TOOTH #1 3RD MOLAR /WISDOM TOOTH WHICH IS BROKEN IN HALF; THE UPPER TOOTH #2ND MOLAR WHICH IS LIKE THE BOTTOM TEETH. (B)(6) 2019 PT TREATMENT CASE REPORT: (B)(6) REPAIR. FOUR VISITS TO REPAIR, EXTRACT, TREAT DAMAGED TEETH TO UPPER AND LOWER TEETH. DENTIST SHARED THAT TEETH SHOULD HAVE BEEN EXTRACTED AND REPAIRED PRIOR TO KNOWN BRACES TO STRAIGHTEN TEETH. HE WAS UNSURE OF THE DENTAL PRACTICES OF SMILES DIRECT CLUB AS BEING AUTHENTIC. FATHER HAD PERIODONTAL DISEASE FOR YEARS IN WHICH WAS DISCLOSED TO SMILES DIRECT CLUB. IN EMAIL AFOREMENTIONED, THEY HAD KNOWLEDGE THROUGH THEIR IMPRESSIONS AND IMAGE THAT THEY WERE AWARE OF DECAY AND DAMAGE OF TEETH AND APPROVED THEIR ALIGNERS TO PROVIDE STRAIGHTENING OF TEETH. TREATMENT START: (B)(6) 2017, STOP: (B)(6) 2019. COMPOUNDED: YES. FDA SAFETY REPORT ID# (B)(4).

**Concomitant Medical****Products (F):****INITIAL REPORTER INFORMATION (G)**

<b>Name (G1):</b>	[REDACTED]	<b>Company (G1):</b>		<b>Email (G1):</b>	[REDACTED]
		<b>Address (G1):</b>	[REDACTED]	<b>Phone (G1):</b>	[REDACTED]
			[REDACTED]	<b>Fax (G1):</b>	
			[REDACTED]		
<b>Health Professional (G2):</b>	*	<b>Also Reported To (G4):</b>	Manufacturer:		
			User Facility: N		
<b>Occupation (G3):</b>	PATIENT	<b>NOT Releasable (G5):</b>	Distributor/Importer:		
			N		



# Exhibit 20



[FDA Home](#)<sup>3</sup> [Medical Devices](#)<sup>4</sup> [Databases](#)<sup>5</sup>

## MAUDE Adverse Event Report: SMILE DIRECT CLUB / ALIGN TECHNOLOGY, INC. SMILE DIRECT CLUB ALIGNERS ALIGNER, SEQUENTIAL



[510\(k\)](#)<sup>7</sup> [DeNovo](#)<sup>8</sup> [Registration & Listing](#)<sup>9</sup> [Adverse Events](#)<sup>10</sup> [Recalls](#)<sup>11</sup> [PMA](#)<sup>12</sup> [HDE](#)<sup>13</sup> [Classification](#)<sup>14</sup> [Standards](#)<sup>15</sup>  
[CFR Title 21](#)<sup>16</sup> [Radiation-Emitting Products](#)<sup>17</sup> [X-Ray Assembler](#)<sup>18</sup> [Medsun Reports](#)<sup>19</sup> [CLIA](#)<sup>20</sup> [TPLC](#)<sup>21</sup>

**SMILE DIRECT CLUB / ALIGN TECHNOLOGY, INC. SMILE DIRECT CLUB ALIGNERS ALIGNER, SEQUENTIAL** [Back to Search Results](#)

**Device Problem** Product Quality Problem (1506)

**Patient Problem** No Clinical Signs, Symptoms or Conditions (4582)

**Event Date** 03/06/2021

**Event Type** Injury

**Event Description**

I started using smile direct club's aligners on (b)(6) 2019. They continuously have to re-scan my teeth and send more aligners. These aligners literally do not work - they have not moved my teeth at all. These are medical devices and i haven't seen or spoken to a dentist or orthodontist over there at all. The only people who will talk to me are sales. This company needs to be shutdown. They are selling a medical device without the patient seeing a real medical professional and its causing harm in multiple ways. How in the world are they allowed to continue this?. Fda safety report id # (b)(4).

### Search Alerts/Recalls<sup>22</sup>

[New Search](#) | [Submit an Adverse Event Report](#)<sup>23</sup>

**Brand Name** SMILE DIRECT CLUB ALIGNERS

**Type of Device** ALIGNER, SEQUENTIAL

**Manufacturer (Section D)** SMILE DIRECT CLUB / ALIGN TECHNOLOGY, INC.

**MDR Report Key** 11453448

**MDR Text Key** 239170309

**Report Number** MW5099891

**Device Sequence Number** 1

**Product Code** NXC<sup>24</sup>

**Combination Product (y/n)** Y

**Reporter Country Code** US

**Number of Events Reported** 1

**Summary Report (Y/N)** N

**Report Source** Voluntary

**Reporter Occupation** Patient

**Type of Report** Initial

**Report Date** 03/06/2021

**1 Device was Involved in the Event**

**1 Patient was Involved in the Event**

**Date FDA Received** 03/09/2021

**Is this an Adverse Event Report?** Yes

**Is this a Product Problem Report?** Yes

**Device Operator**

**Was Device Available for Evaluation?** Yes

**Is the Reporter a Health Professional?** No Answer provided

**Was the Report Sent to FDA?**

**Event Location** No Information

**Was Device Evaluated by Manufacturer?**

**Is the Device Single Use?**

**Is This a Reprocessed and Reused Single-Use Device?**

**Type of Device Usage**

### Patient Treatment Data

**Date Received:** 03/09/2021 **Patient Sequence Number:** 1

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Page Last Updated: 09/30/2022

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Silver Spring, MD 20993  
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